



SB 486 Safe Needle Disposal Plan for 2016 – 2017

Submitted to:

**Department of Resources Recycling and Recovery
(CalRecycle)**

01 July 2016

Background

The State of California has enacted two laws to address home generated sharps disposal. The first law (SB 1305), makes it illegal for any person in the state of California to dispose of home generated sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in an approved sharps container. This law became effective September 1, 2008. In 2009, California enacted (SB 486) which requires any pharmaceutical manufacturer that sells or distributes medication that is self-injected at home through the use of hypodermic needles and other similar devices to submit to the board, or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of waste devices. This plan is due on July 1, 2010 and annually thereafter.

Dr. Reddy's Laboratories, Inc. Self-Injectable Products

Subject To These Regulations in California

Dr. Reddy's Laboratories, Inc. currently markets, distributes, and/or sells two self-injectable products in the State of California. The generic names of these products are fondaparinux sodium injection (subcutaneous) and sumatriptan injection (subcutaneous).

Fondaparinux sodium injection is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE): in patients undergoing hip fracture surgery, including extended prophylaxis; in patients undergoing hip replacement surgery; in patients undergoing knee replacement surgery; in patients undergoing abdominal surgery who are at risk for thromboembolic complications. Fondaparinux sodium injection is indicated for the treatment of acute deep vein thrombosis when administered in conjunction with warfarin sodium. Fondaparinux sodium injection is indicated for the treatment of acute pulmonary embolism when administered in conjunction with warfarin sodium when initial therapy is administered in the hospital.

Sumatriptan injection is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache. **Limitations of Use:** Use only if a clear diagnosis of migraine or cluster headache has been established. If a patient has no response to the first migraine attack treated with sumatriptan injection, reconsider the diagnosis of migraine before sumatriptan injection is administered to treat any subsequent attacks. Sumatriptan injection, is not indicated for the prevention of migraine attacks

Dr. Reddy's Laboratories, Inc. Supports Safe Collection

and Proper Disposal of Home Generated Sharps

Dr. Reddy's Laboratories, Inc. supports appropriate and safe disposal of home-generated waste sharps. Patient safety and needle stick injury prevention were given serious consideration as the above-mentioned products were being developed.

Fondaparinux

During the development of fondaparinux sodium injection (subcutaneous), Dr. Reddy's Laboratories, Inc. employed safe needle technology in order to protect patients and those assisting in the disposal of waste sharps. Specifically, fondaparinux sodium injection uses a 27 gauge needle that is only a half-inch long and an automatic needle protection system covers the needle after the injection. The steps to activate the automatic needle protection system are described in the fondaparinux sodium injection (subcutaneous) Patient Information Leaflet.

Automatic Needle Protection System:

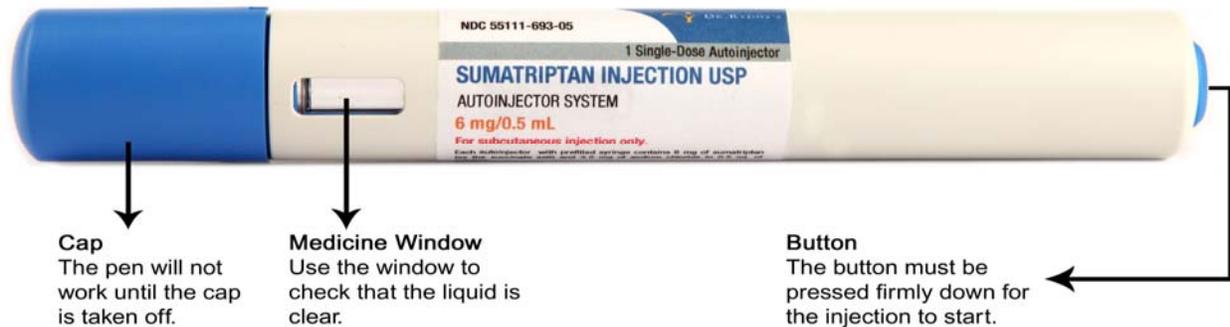
The different parts of fondaparinux sodium safety syringe are:	
<ol style="list-style-type: none">1. Rigid Needle Shield2. Plunger3. Finger-grip4. Safety shield	
Syringe BEFORE USE	Syringe AFTER USE
	

Sumatriptan

Sumatriptan injection autoinjector system is available for use with a 6 mg prefilled syringe to facilitate self-administration in patients using the 6 mg dose. With this device, the needle penetrates approximately ¼ inch (5 to 6 mm). The steps to activate the autoinjector system are described in the sumatriptan injection (subcutaneous) Patient Information and Instructions for Use.

About the Autoinjector Pen

The parts of the pen are shown in this picture.



Patient Education Materials:

Patients who self-inject Dr. Reddy's Laboratories, Inc. products at home should receive instructions from their healthcare professionals on how to use these products properly. The full prescribing information is available to healthcare professionals. Patients should read the Patient Information Leaflet that comes with each product before they start taking each product and each time the prescription is refilled as there may be new information.

Dr. Reddy's Laboratories, Inc. has also created a patient specific website for sumatriptan injection (subcutaneous) at www.drreddys.com/products/NA/sumatriptan.html. This website provides patients with the most important information they need to know from Dr. Reddy's Laboratories. The information on this website does not take the place of talking with the patient's doctor about the medical conditions or treatments. Patients can view sumatriptan self-administration instructions in English in text or as a video.

Patients and caregivers can also contact a Dr. Reddy's Laboratories, Inc. representative at 1-888-375-3784. Pharmacists are available Monday through Friday 8:00 am to 10:00 pm ET to assist with questions about these products.

Disposal:

Patients and consumers have several options available to them to safely dispose sharps waste.

Patients may visit California's CalRecycle website at <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm> to become familiar with all disposal options available and select the option that is most convenient. Below are disposal options detailed on the California CalRecycle website:

- Patients may use the [Disposal Directory \(FacIT\) for Sharps and Medication](http://www.calrecycle.ca.gov/facit/facility/search.aspx) (via link <http://www.calrecycle.ca.gov/facit/facility/search.aspx>). In this directory, you may locate facilities that collect sharps for disposal near to where you live or work. Collection programs include:

- **Pharmacies.** Some drug stores take back their customers' needles, especially in small quantities.
- **Hospitals.** Hospitals may take back sharps from patients using regular outpatient services.
- **Local Household Hazardous Waste Programs.** Call your local household hazardous waste agency and ask if they collect needles (sharps) at their collection facilities or on household hazardous waste days. You can also look for this information here:
 - Your local white pages' government section may list your city's or county's household hazardous waste department.
 - Visit the [Earth 911.org](http://Earth911.org) website or call 1-800-CLEANUP (1-800-253-2687), a service of Earth 911.
 - Visit the [Local Enforcement Agency Directory](#) on this website.
- [Local Jurisdiction Sharps Collection Programs.](#) A file showing a sampling of local jurisdictions' sharps collection programs and containing contacts, e-mail addresses, program summaries, and outreach materials. This spreadsheet could help jurisdictions that don't currently have collection programs to set up their own sharps collection program.
- **Needle Destruction Devices.** The U.S. Food and Drug Administration (FDA) currently only lists the ["Disintegrator"](#) as a needle destruction device approved for use by self-injectors.
- **Mail-Back Service.** A list of sharps waste mail-back services authorized for use in California is available from the [California Department Of Public Health \(CDPH\)](#) (PDF, 90 KB).
- **Sharps Containers.** The California Department of Public Health Medical Waste Management Program is recommending the use of [sharps containers approved by the FDA](#). After accessing the FDA website, type "sharps" in the search box. The container names will display alphabetically.

For More Information

Stay informed about the latest developments in CalRecycle's efforts to promote safe disposal of sharps waste.

- **Listserv:** To receive periodic information about sharps, subscribe to the [Sharps and Medication Disposal Listserv](#).
- **Contact:** Please contact pharmasharps@calrecycle.ca.gov for questions or more information.

Company Contact Information:

If you would like assistance from Dr. Reddy's Laboratories, Inc. in identifying your disposal options, please contact a Dr. Reddy's Laboratories, Inc. representative at 1-888-375-3784. Representatives are available to assist patients with questions about each of these products, including product administration and medical waste disposal.

Dr. Reddy's Laboratories, Inc. remains committed to help facilitate the safe disposal of its products and will continue to evaluate feedback and make modifications to this plan as needed.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SUMATRIPTAN INJECTION safely and effectively. See full prescribing information for SUMATRIPTAN INJECTION.

SUMATRIPTAN Injection, for subcutaneous use Initial U.S. Approval: 1992

INDICATIONS AND USAGE

Sumatriptan injection is a serotonin (5-HT_{1B/1D}) receptor agonist (triptan) indicated for:

- Acute treatment of migraine with or without aura in adults (1)
- Acute treatment of cluster headache in adults (1)

Limitations of Use:

- Use only if a clear diagnosis of migraine or cluster headache has been established (1)
- Not indicated for the prophylactic therapy of migraine or cluster headache attacks (1)

DOSEAGE AND ADMINISTRATION

- For subcutaneous use only (2.1)
- Acute treatment of migraine: single dose of 1 to 6 mg (2.1)
- Acute treatment of cluster headache: single dose of 6 mg (2.1)
- Maximum dose in a 24-hour period: 12 mg, separate doses by at least 1 hour (2.1)
- Patients receiving doses other than 6 mg: Use the 6 mg single-dose vial (2.3)

DOSEAGE FORMS AND STRENGTHS

- Injection: 6 mg single-dose prefilled syringe assembled in an autoinjector (3)

CONTRAINDICATIONS

- History of coronary artery disease or coronary vasospasm (4)
- Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders (4)

- History of stroke, transient ischemic attack, or hemiplegic or basilar migraine (4)
- Peripheral vascular disease (4)
- Ischemic bowel disease (4)
- Uncontrolled hypertension (4)
- Recent (within 24 hours) use of another 5-HT₁ agonist (e.g., another triptan) or of an ergotamine-containing medication (4)

- Concurrent or recent (past 2 weeks) use of monoamine oxidase-A-inhibitor (4)
- Known hypersensitivity to sumatriptan (4)
- Hypersensitivity to sumatriptan injection (angioedema and anaphylaxis seen) (4)
- Severe hepatic impairment (4)

WARNINGS AND PRECAUTIONS

- Myocardial ischemia/infarction and Prinzmetal's angina: Perform cardiac evaluation in patients with multiple cardiovascular risk factors (5.1)
- Arrhythmias: Discontinue sumatriptan injection if occurs (5.2)
- Chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Generally not associated with myocardial ischemia; evaluate for coronary artery disease in patients at high risk (5.3)
- Cerebral hemorrhage, subarachnoid hemorrhage, and stroke: Discontinue sumatriptan injection if occurs (5.4)
- Gastrointestinal ischemic reactions and peripheral vasospastic reactions: Discontinue sumatriptan injection if occurs (5.5)
- Medication overuse headache: Detoxification may be necessary (5.6)
- Serotonin syndrome: Discontinue sumatriptan injection if occurs (5.7)
- Seizures: Use with caution in patients with epilepsy or a lowered seizure threshold (5.10)

ADVERSE REACTIONS

Most common adverse reactions (> 5% and > placebo) were injection site reactions, tingling, dizziness/vertigo, warm/not sensation, burning sensation, feeling of heaviness, pressure sensation, flushing, feeling of tightness, and numbness (6.1)

To report suspected adverse reactions, contact Dr. Reddy's Laboratories Inc. at 1-866-376-3784 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm (8.1)

See 17 FOR PATIENT COUNSELING INFORMATION AND FDA-APPROVED patient labeling.

CONTRAINDICATIONS

- Myocardial ischemia, myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetal's angina (see Warnings and Precautions (5.1))
- Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders (see Warnings and Precautions (5.2))
- History of stroke or transient ischemic attack (TIA) or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke (see Warnings and Precautions (5.4))
- Peripheral vascular disease (see Warnings and Precautions (5.5))
- Ischemic bowel disease (see Warnings and Precautions (5.5))
- Uncontrolled hypertension (see Warnings and Precautions (5.8))
- Recent use (i.e., within 24 hours) of ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), or another 5-hydroxytryptamin, (5-HT₁) agonist (see Drug Interactions (7.1, 7.3))
- Concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent (within 2 weeks) use of an MAO-A inhibitor (see Drug Interactions (7.2), Clinical Pharmacology (12.3))
- Hypersensitivity to sumatriptan injection (angioedema and anaphylaxis seen) (see Warnings and Precautions (5.8))
- Severe hepatic impairment (see Clinical Pharmacology (12.3))

WARNINGS AND PRECAUTIONS

5.1 Myocardial Ischemia, Myocardial Infarction, and Prinzmetal's Angina
The use of sumatriptan injection is contraindicated in patients with ischemic or vasospastic CAD. There have been rare reports of serious cardiac adverse reactions, including acute myocardial infarction, occurring within a few hours following administration of sumatriptan injection. Some of these reactions occurred in patients without known CAD. Sumatriptan injection may cause coronary artery vasospasm (Prinzmetal's angina), even in patients without a history of CAD.

Perform a cardiovascular evaluation in triptan-naïve patients who have multiple cardiovascular risk factors (e.g., increased age, diabetes, hypertension, smoking, obesity, strong family history of CAD) prior to receiving sumatriptan injection. If there is evidence of CAD or coronary artery vasospasm, sumatriptan injection is contraindicated. For patients with multiple cardiovascular risk factors who have a negative cardiovascular evaluation, consider administration of the first dose of sumatriptan injection in a medically supervised setting and performing an electrocardiogram (ECG) immediately following administration of sumatriptan injection. For such patients, consider periodic cardiovascular evaluation in intermittent long-term users of sumatriptan injection.

5.2 Arrhythmias

Life-threatening disturbances of cardiac rhythm, including ventricular tachycardia and ventricular fibrillation leading to death, have been reported within a few hours following the administration of 5-HT₁ agonists. Discontinue sumatriptan injection if these disturbances occur. Sumatriptan injection is contraindicated in patients with Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders.

5.3 Chest, Throat, Neck, and/or Jaw Pain/Tightness/Pressure
Sensations of tightness, pain, pressure, and heaviness in the precordium, throat, neck, and jaw commonly occur after treatment with sumatriptan injection and are usually non-cardiac in origin. However, perform a cardiac evaluation if these patients are at high cardiac risk. The use of sumatriptan injection is contraindicated in patients with CAD and those with Prinzmetal's variant angina.

5.4 Cardiovascular Events

Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-HT₁ agonists, and some have resulted in fatalities. In a number of cases, it appears possible that the cerebrovascular events were primary, the 5-HT₁ agonist having been administered in the incorrect belief that the symptoms experienced were a consequence of migraine when they were not. Also, patients with migraines may be at increased risk of certain cerebrovascular events (e.g., stroke, hemorrhage, TIA). Discontinue sumatriptan injection if a cerebrovascular event occurs. Before treating headaches in patients not previously diagnosed with migraine or cluster headache or in patients who present with atypical symptoms, exclude other potentially serious neurological conditions. Sumatriptan injection is contraindicated in patients with a history of stroke or TIA.

5.5 Other Vasospasm Reactions

Sumatriptan injection may cause non-coronary vasospastic reactions, such as peripheral vascular ischemia, gastrointestinal vasospasm and infarction (resulting with abdominal pain and bloody diarrhea), ischemic infarction, and Raynaud's syndrome. In patients who experience symptoms or signs suggestive of non-coronary vasospasm reaction following the use of any 5-HT₁ agonist, rule out a vasospastic reaction before receiving additional sumatriptan injections.

Reports of transient and permanent loss of vision and significant partial vision loss have been reported with the use of 5-HT₁ agonists. Since visual disorders may be part of a migraine attack, a causal relationship between these events and the use of 5-HT₁ agonists have not been clearly established.

5.6 Medication Overuse Headache

Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, or combination of these drugs for 10 or more days per month) may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches, or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drug, and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

5.7 Serotonin Syndrome

Serotonin syndrome may occur with sumatriptan injection, particularly during co-administration with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and MAO inhibitors (see Drug Interactions (7.4)). Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperreflexia), neuromuscular aberrations (e.g., hyperreflexia, incoordination), and/or gastrointestinal symptoms (e.g., nausea/vomiting, diarrhea). The onset of symptoms usually occurs within minutes to hours of receiving a new or a greater dose of a serotonergic medication. Discontinue sumatriptan injection if serotonin syndrome is suspected.

5.8 Increase in Blood Pressure

Significant elevation in blood pressure, including hypertensive crisis with acute impairment of organ systems, has been reported on rare occasions in patients treated with 5-HT₁ agonists, including patients without a history of hypertension. Monitor blood pressure in patients treated with sumatriptan. Sumatriptan injection is contraindicated in patients with uncontrolled hypertension.

5.9 Anaphylactic/Anaphylactoid Reactions

Anaphylactic/anaphylactoid reactions have occurred in patients receiving sumatriptan injection. Such reactions can be life threatening or fatal. In general, anaphylactoid reactions to drugs are more likely to occur in individuals with a history of sensitivity to multiple allergens. Sumatriptan injection is contraindicated in patients with a history of allergy or conditions associated with a lowered seizure threshold.

5.10 Seizures

Seizures have been reported following administration of sumatriptan injection. Some have occurred in patients with either a history of seizures or documented conditions predisposing to seizures. There are also reports in patients where no such predisposing factors are apparent. Sumatriptan injection should be used with caution in patients with a history of epilepsy or conditions associated with a lowered seizure threshold.

6 ADVERSE REACTIONS

The following serious adverse reactions are described below and elsewhere in the labeling:

- Myocardial ischemia, myocardial infarction, and Prinzmetal's angina (see Warnings and Precautions (5.1))
- Arrhythmias (see Warnings and Precautions (5.2))
- Chest, throat, neck, and/or jaw pain/tightness/pressure (see Warnings and Precautions (5.3))
- Cardiovascular events (see Warnings and Precautions (5.4))
- Other vasospasm reactions (see Warnings and Precautions (5.5))
- Medication overuse headache (see Warnings and Precautions (5.6))
- Serotonin syndrome (see Warnings and Precautions (5.7))
- Increase in blood pressure (see Warnings and Precautions (5.8))
- Hypersensitivity reactions (see Contraindications (4), Warnings and Precautions (5.8))
- Seizures (see Warnings and Precautions (5.10))

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Migraine Headache
Table 1 lists adverse reactions that occurred in U.S. placebo-controlled clinical trials in migraine patients (Studies 1 and 2) following either a single 6 mg or 2 mg dose of sumatriptan injection or placebo. Only reactions that occurred at a frequency of 2% or more in groups treated with sumatriptan injection 6 mg and that occurred at a frequency greater than the placebo group are included in Table 1.

Table 1. Adverse Reactions in Placebo-Controlled Trials in Patients with Migraine (Studies 1 and 2)

	Sumatriptan Injection 6 mg Subcutaneous (n = 547) %	Placebo (n = 376) %
Atypical sensations	42	9
Tingling	14	3
Warm/not sensation	11	4
Burning sensation	7	<1
Feeling of heaviness	7	1
Pressure sensation	7	2
Feeling of tightness	6	<1
Numbness	5	2
Feeling strange	2	<1
Tight feeling in head	2	<1
Cardiovascular		
Flushing	7	2
Chest discomfort	6	1
Tightness in chest	4	<1
Pressure in chest	2	<1
Ear, nose, and throat		
Throat discomfort	3	<1
Discomfort: nasal cavity/nosuses	2	<1

continued to next column

Injection site reaction ^a	59	24
Miscellaneous		
Jaw discomfort	2	0
Musculoskeletal		
Weakness	5	<1
Neck pain/tightness	5	<1
Myalgia	2	<1
Neurological		
Dizziness/vertigo	12	4
Drowsiness/lethargy	3	2
Headache	2	<1
Skin		
Sweating	2	1

^a Includes injection site pain, stinging/burning, swelling, erythema, bruising, bleeding. The incidence of adverse reactions in controlled clinical trials was not affected by gender or age of the patients. There were insufficient data to assess the impact of race on the incidence of adverse reactions.

Cluster Headache

In the controlled clinical trials assessing the efficacy of sumatriptan injection as a treatment for cluster headache (Studies 4 and 5), no significant adverse reactions were detected that had not already been identified in trials of sumatriptan injection in patients with migraine. Overall, the frequency of adverse reactions reported in the trials of cluster headache was generally lower than in the migraine trials. Exceptions include reports of parosmia (5% sumatriptan injection, 0% placebo), nausea and vomiting (4% sumatriptan injection, 0% placebo), and bradycardia (1% sumatriptan injection, 0% placebo).

8.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of sumatriptan tablets, sumatriptan nasal spray, and sumatriptan injection. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiovascular

Hypertension, palpitations.

Neurological

Dizziness.

7 DRUG INTERACTIONS

7.1 Ergot-containing Drugs

Ergot-containing drugs have been reported to cause prolonged vasospastic reactions. Because these effects may be additive, use of ergotamine-containing or ergot-type medications (like dihydroergotamine or methysergide) and sumatriptan injection within 24 hours of each other is contraindicated (see Contraindications (4)).

7.2 Monoamine Oxidase-A Inhibitors

MAO-A inhibitors increase systemic exposure by 2-fold. Therefore, the use of sumatriptan injection in patients receiving MAO-A inhibitors is contraindicated (see Contraindications (4)).

7.3 Other 5-HT₁ Agonists

Because other 5-HT₁ agonists may be additive, co-administration of sumatriptan injection and other 5-HT₁ agonists (e.g., triptans) within 24 hours of each other is contraindicated.

7.4 Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors and Serotonin Syndrome

Cases of serotonin syndrome have been reported during co-administration of triptans and SSRIs, or SNRIs, TCAs, and MAO inhibitors (see Warnings and Precautions (5.7)).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

There are no adequate and well-controlled trials of sumatriptan injection in pregnant women. In developmental toxicity studies in rats and rabbits, oral administration of sumatriptan to pregnant animals was associated with embryofetality, fetal abnormalities, and pup mortality. When administered by the intravenous route to pregnant rabbits, sumatriptan was embryolethal. Sumatriptan injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Oral administration of sumatriptan to pregnant rats during the period of organogenesis resulted in an increased incidence of fetal blood vessel (cardiothoracic and umbilical) abnormalities. The highest no-effect dose for embryofetal developmental toxicity in rats was 50 mg/kg/day, or approximately 100 times the single maximum recommended human dose (MRHD) of 6 mg administered subcutaneously on a mg/m² basis. Oral administration of sumatriptan to pregnant rabbits during the period of organogenesis resulted in increased incidences of embryofetality and fetal cardiovascular and skeletal abnormalities. Intravenous administration of sumatriptan to pregnant rabbits during the period of organogenesis resulted in an increased incidence of embryofetality. The highest oral and intravenous no-effect doses for developmental toxicity in rabbits were 15 and 0.75 mg/kg/day, or approximately 50 and 2 times, respectively, the single MRHD of 6 mg administered subcutaneously on a mg/m² basis.

8.2 Nursing Mothers

Sumatriptan is excreted in human milk following subcutaneous administration. Infant exposure to sumatriptan can be minimized by avoiding breastfeeding for 12 hours after treatment with sumatriptan injection.

8.3 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Sumatriptan injection is not recommended for use in patients younger than 18 years of age.

Two controlled clinical trials evaluated sumatriptan nasal spray (5 to 20 mg) in 1,246 pediatric migraineurs 12 to 17 years of age who treated a single attack. The trials did not establish the efficacy of sumatriptan nasal spray compared with placebo in the treatment of migraine in pediatric patients. Adverse reactions reported in pediatric patients were similar to those reported in adults.

Five controlled clinical trials (2 single-attack trials, 3 multiple-attack trials) evaluating oral sumatriptan (25 to 100 mg) in pediatric patients 12 to 17 years of age enrolled a total of 701 pediatric migraineurs. These trials did not establish the efficacy of oral sumatriptan compared with placebo in the treatment of migraine in pediatric patients. Adverse reactions observed in these clinical trials were similar in nature to those reported in clinical trials in adults. The frequency of all adverse reactions in these patients appeared to be both dose- and age-dependent, with younger patients reporting reactions more commonly than older pediatric patients.

Postmarketing experience documents that serious adverse reactions have occurred in the pediatric population after use of subcutaneous, oral, and/or intranasal sumatriptan. These reports include reactions similar in nature to those reported among adults, including stroke, visual loss, and myocardial infarction. Clinical data to date demonstrate the frequency of serious adverse reactions in pediatric patients who might receive subcutaneous, oral, or intranasal sumatriptan are not presently available.

8.4 Geriatric Use

Clinical trials of sumatriptan injection did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

A cardiovascular evaluation is recommended for geriatric patients who have other cardiovascular risk factors (e.g., diabetes, hypertension, smoking, obesity, strong family history of CAD) prior to receiving sumatriptan injection (see Warnings and Precautions (5.1)).

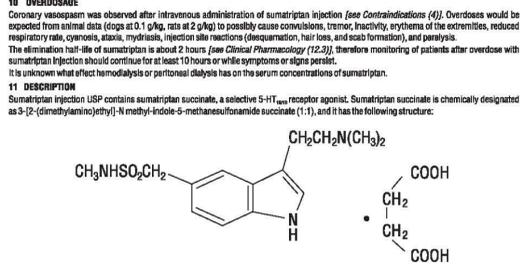
10 OVERDOSAGE

Coronary vasospasm was observed after intravenous administration of sumatriptan injection (see Contraindications (4)). Overdose would be expected from clinical data (dog at 0.1 mg/kg, rats at 2 mg/kg) to possibly cause convulsions, tremor, bradycardia, symptoms of the extremities, reduced respiratory rate, cyanosis, ataxia, mydriasis, injection site reactions (dequamation, hair loss, and scab formation), and paralysis.

The elimination half-life of sumatriptan is about 2 hours. In an off-pump cardiac surgery patient, sumatriptan was administered intravenously at 100 mg. The elimination half-life of sumatriptan injection solution contains 6 mg of sumatriptan (base) in the succinate salt and 3 mg of sodium chloride in Water for Injection. The pH range of the solutions is approximately 4.2 to 5.3. The osmolality of the injection is between 275 and 315 mOsm/kg.

11 DESCRIPTION

Sumatriptan injection USP contains sumatriptan succinate, a selective 5-HT_{1B/1D} receptor agonist. Sumatriptan succinate is chemically designated as 5-[2-(dimethylamino)ethyl]-N-methyl-DL-methanesulfonamide succinate (1:1), and it has the following structure:



The molecular formula is C₁₇H₂₁N₃O₆·2H₂O, representing a molecular weight of 413.5. Sumatriptan succinate USP is a white or almost white powder and is freely soluble in water, sparingly soluble in methanol, practically insoluble in methylene chloride. Sumatriptan injection USP is a clear, colorless to pale yellow, free from visible particulate matter, sterile nonpyrogenic solution for subcutaneous injection. Each 3-mL of sumatriptan injection solution contains 6 mg of sumatriptan (base) in the succinate salt and 3 mg of sodium chloride in Water for Injection. The pH range of the solutions is approximately 4.2 to 5.3. The osmolality of the injection is between 275 and 315 mOsm/kg.

PHARMACIST - DETACH FROM HERE

provider

For adults, the usual dose is a single injection given just below the skin.

You should give an injection as soon as the symptoms of your headache start, but it may be given at any time during a migraine or cluster headache attack.

If you did not get any relief after the first injection, do not give a second injection without first talking with your healthcare provider.

If your headache comes back or you only get some relief after your first injection, you can take a second injection 1 hour after the first injection, but no sooner.

Do not take more than 12 mg in a 24-hour period.

If you use too much sumatriptan injection, call your healthcare provider or go to the nearest hospital emergency room right away.

You should write down when you have headaches and when you take sumatriptan injection, so you can talk with your healthcare provider about how sumatriptan injection is working for you.

What should I avoid while taking sumatriptan injection?
Sumatriptan can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything where you need to be alert.

What are the possible side effects of sumatriptan injection?
Sumatriptan may cause serious side effects. See "What is the most important information I should know about sumatriptan injection?"

These serious side effects include:

- changes in color or sensation in your fingers and toes (Raynaud's syndrome)
- stomach and intestinal problems (gastrointestinal and colonic ischemic events). Symptoms of gastrointestinal and colonic ischemic events include:
- sudden or severe stomach pain
- stomach pain after meals
- weight loss
- nausea or vomiting
- constipation or diarrhea
- bloody diarrhea
- fever
- problems with blood circulation to your legs and feet (peripheral vascular ischemia). Symptoms of peripheral vascular ischemia include:
- cramping and pain in your legs or hips
- feeling of heaviness or tightness in your leg muscles
- burning or aching pain in your feet or toes while resting
- numbness, tingling, or weakness in your legs or feet
- cold feeling or color changes in 1 or both legs or feet
- limes (farcy bumps); swelling of your tongue, mouth, or throat
- medication overuse headaches. Some people who use too many sumatriptan injections may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with sumatriptan.
- serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using sumatriptan injection, especially if sumatriptan injection is used with antidepressant medicines called SSRIs or SNRIs.

Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:

- mental changes such as seeing things that are not there (hallucinations), agitation, or coma
- fast heartbeat
- changes in blood pressure
- high body temperature
- light body temperature
- tight muscles
- tremor
- trouble walking
- seizures. Seizures have happened in people taking sumatriptan injection who have never had seizures before.

Talk with your healthcare provider about your chance of having seizures while you take sumatriptan injection.

The most common side effects of sumatriptan injection include:

- pain or redness at your injection site
- tingling or numbness in your fingers or toes
- dizziness
- warm, hot, burning feeling to your face (flushing)
- discomfort or stiffness in your neck
- feeling weak, drowsy, or tired
- Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
- These are not all the possible side effects of sumatriptan injection. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store sumatriptan injection?

- Store at 25°C (77°F); excursions permitted 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).
- Store your medicines away from light.
- Keep your medicine in the packaging or carrying case provided with it.

Keep sumatriptan injection and all medicines out of the reach of children.

General information about the safe and effective use of sumatriptan injection

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use sumatriptan injection for a condition for which it was not prescribed. Do not give sumatriptan injection to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about sumatriptan injection. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about sumatriptan injection that is written for healthcare professionals.

For more information, call 1-888-376-3784.

What are the ingredients in sumatriptan injection?
Active ingredients: sumatriptan succinate USP
Inactive ingredients: sodium chloride, water for injection

The other brands listed are trademarks of their respective owners and are not trademarks of Dr. Reddy's Laboratories Limited. The makers of these brands are not affiliated with and do not endorse Dr. Reddy's Laboratories Limited or its products.

Continued on other side

PATIENT INFORMATION

Sumatriptan injection USP

Read this Patient Information before you start taking sumatriptan and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about sumatriptan injection?

Sumatriptan can cause serious side effects, including:

- heart attack and other heart problems. Heart problems may lead to death.
- Stop taking sumatriptan and get emergency medical help right away if you have any of the following symptoms of a heart attack:
- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Sumatriptan is not for people with risk factors for heart disease unless a heart exam is done and shows no problem. You have a higher risk for heart disease if you:

- have high blood pressure
- have high cholesterol levels
- smoke
- are overweight
- have diabetes
- have a family history of heart disease

What is sumatriptan?

Sumatriptan is a prescription medicine used to treat acute migraine headaches with or without aura and acute cluster headaches in adults who have been diagnosed with migraine or cluster headaches.

Sumatriptan is not used to treat other types of headaches such as hemiplegic tic, make you unable to move on one side of your body) or basilar (rare form of migraine with aura) migraines.

Sumatriptan is not used to prevent or decrease the number of migraine or cluster headaches you have.

It is not known if sumatriptan is safe and effective in children under 18 years of age.

Who should not take sumatriptan injection?

Do not take sumatriptan injection if you have:

- heart problems or a history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidneys (peripheral vascular disease)
- uncontrolled high blood pressure
- severe liver problems
- have migraines or basilar migraines. If you are not sure if you have these types of migraines, ask your healthcare provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with your blood circulation
- taken any of the following medicines in the last 24 hours:
- almotriptan (AMERT)
- frovatriptan (FROVA)
- eletriptan (AMERGE)
- naratriptan (AMAXALT, MAXALT-MLT)
- rizatriptan (MAXALT, MAXALT-MLT)
- sumatriptan and naratriptan (TREQXMET)
- ergotamines (CAREGOT, ERGOMAR, MIGERGOT)
- dihydroergotamine (D.H.E. 45, MGRMANTAL)

Ask your healthcare provider if you are not sure if your medicine is listed above.

What should I tell my healthcare provider before taking sumatriptan injection?

Before you take sumatriptan, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure
- have high cholesterol
- have diabetes
- are overweight
- have heart problems or family history of heart problems or stroke
- have kidney problems
- have had epilepsy or seizures
- are not using effective birth control

become pregnant while taking sumatriptan

are breastfeeding or plan to breastfeed. Sumatriptan passes into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take sumatriptan.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Sumatriptan and certain other medicines can affect each other, causing serious side effects.

Especially tell your healthcare provider if you take antidepressant medicines called:

- selective serotonin reuptake inhibitors (SSRIs)
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- tricyclic antidepressants (TCAs)
- monoamine oxidase inhibitors

* P<0.05 versus placebo.
 † A successful outcome in terms of clinical disability was defined prospectively as ability to work, mildly impaired or ability to work and function normally.
 ‡ Includes patients that may have received an additional placebo injection 1 hour after the initial injection.
 § Includes patients that may have received an additional 6 mg of sumatriptan injection 1 hour after the initial injection.
 ¶ Sumatriptan injection also relieved photophobia, phonophobia (sound sensitivity), nausea, and vomiting associated with migraine attacks. Similar efficacy was seen when patients self-administered sumatriptan injection using an autoinjector.
 †† The efficacy of sumatriptan injection was unaffected by whether or not the migraine was associated with aura, duration of attack, gender or age of the patient, or concomitant use of common migraine prophylactic drugs (e.g., beta-blockers).

14.2 Cluster Headache
 The efficacy of sumatriptan injection in the acute treatment of cluster headache was demonstrated in 2 randomized, double-blind, placebo-controlled, 2-pilot crossover trials (Studies 4 and 5). Patients 21 to 65 years of age were enrolled and were instructed to treat a moderate to very severe headache within 10 minutes of onset. Headache relief was defined as a reduction in headache severity to mild or no pain. In both trials, the proportion of individuals gaining relief at 10 or 15 minutes was significantly greater among patients receiving 6 mg of sumatriptan injection compared with those who received placebo (see Table 4).

Table 4. Proportion of Patients with Cluster Headache Relief by Time in Studies 4 and 5

	Study 4		Study 5	
	Placebo (n = 28)	Sumatriptan injection 6 mg (n = 28)	Placebo (n = 28)	Sumatriptan injection 6 mg (n = 28)
Patients with pain relief (n/total)				
5 Minutes post-injection	0%	21%	7%	23%*
10 Minutes post-injection	10%	49%*	26%	49%*
15 Minutes post-injection	20%	74%*	35%	75%*

* P<0.05.
 (n = Number of headache treated)
 † An estimate of the cumulative probability of a patient with a cluster headache obtaining relief after being treated with either sumatriptan injection or placebo is presented in Figure 1.



* The figure uses Kaplan-Meier (product limit) Survival Plot. Patients taking rescue medication were censored at 15 minutes. The plot was constructed with data from patients who either appeared relief or did not require (request) rescue medication within a period of 2 hours following treatment. As a consequence, the data in the plot are derived from only a subset of the 258 headaches treated (rescue medication was required in 52 of the 127 placebo-treated headaches and 15 of the 151 headaches treated with sumatriptan injection). Other data suggest that treatment with sumatriptan injection is not associated with an increase in early recurrence of headache and has little effect on the incidence of later-occurring headaches (i.e., those occurring after 2, but before 18 or 24 hours).

18 HOW SUPPLIED/STORAGE AND HANDLING
 Sumatriptan Injection USP contains sumatriptan (base) as the succinate salt and is supplied as a clear, colorless to pale yellow, sterile, nonpyrogenic solution as follows:
 Sumatriptan Injection USP Autoinjector System includes 2 Autoinjectors, each with an associated single-dose prefilled syringe which contains 5 mg of sumatriptan (as the succinate salt) and 3.5 mg of sodium chloride in 0.5 mL of solution.
 Store at 25°C (77°F); excursions permitted 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature). Protect from light.

17 PATIENT COUNSELING INFORMATION
 Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).
Risk of Myocardial Ischemia and/or Infarction, Prolonged QTc Interval, Other Vasospasm-Related Events, Arrhythmias, and Cardiovascular Events
 Inform patients that sumatriptan injection may cause serious cardiovascular side effects such as myocardial infarction or stroke. Although serious cardiovascular events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, irregular heartbeat, significant rise in blood pressure, weakness, and slurring of speech and should seek for medical advice if any indicative sign or symptoms are observed. Advise patients of the importance of this follow-up (see Warnings and Precautions (5.1, 5.2, 5.4, 5.5, 5.8)).

Anaphylactic/Anaphylactoid Reactions
 Inform patients that anaphylactic/anaphylactoid reactions have occurred in patients receiving sumatriptan injection. Such reactions can be life threatening or fatal. In general, anaphylactic reactions to drugs are more likely to occur in individuals with a history of sensitivity to multiple allergens (see Contraindications (4), Warnings and Precautions (5)).

Concomitant Use with Other Triptans or Ergot Medications
 Inform patients that use of sumatriptan injection within 24 hours of another triptan or an ergot-type medication (including dihydroergotamine or methysergide) is contraindicated (see Contraindications (4), Drug Interactions (7.1, 7.3)).

Serotonin Syndrome
 Caution patients about the risk of serotonin syndrome with the use of sumatriptan injection or other triptans, particularly during combined use with SSRIs, SNRIs, TCAs, and MAO inhibitors (see Warnings and Precautions (5.7), Drug Interactions (7.4)).

Medication Overdose Headache
 Inform patients that use of sumatriptan injection for 10 or more days per month may lead to an exacerbation of headache and encourage patients to record headache frequency and drug use (e.g., by keeping a headache diary) (see Warnings and Precautions (5.6)).

Pregnancy
 Inform patients that sumatriptan injection should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus (see Use in Specific Populations (8.1)).

Nursing Mothers
 Advise patients to notify their healthcare provider if they are breastfeeding or plan to breastfeed (see Use in Specific Populations (8.3)).

Ability to Perform Complex Tasks
 Treatment with sumatriptan injection may cause somnolence and dizziness; instruct patients to evaluate their ability to perform complex tasks after administration of sumatriptan injection.

How to Use Sumatriptan Injection
 Instruct patients to read the Instructions for Use before starting therapy. Provide patients instruction on the proper use of sumatriptan injection if they are able to self-administer sumatriptan injection in medically unsupervised situations. Instruct patients on storage and disposal of the pen (see How Supplied/Storage and Handling (16)).

Inform patients that the needle in the autoinjector penetrates approximately 1/4 of an inch (5 to 6 mm). Inform patients that the injection is intended to be given subcutaneously and intramuscular or intravenous delivery should be avoided. Instruct patients to use injection sites with an adequate skin and subcutaneous thickness to accommodate the length of the needle.

Rx Only
 Manufactured by:
 Gland Pharma Limited
 D.P. Pally - 500 043 INDIA
 Manufactured for:
 Dr. Reddy's Laboratories Limited
 Bachupally - 500 090 INDIA

Revised: 1215

PATIENT INFORMATION
 Sumatriptan Injection USP
 Read this Patient Information before you start taking sumatriptan injection and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about sumatriptan injection?
 Sumatriptan can cause serious side effects, including:
 Heart attack and other heart problems. Heart problems may lead to death.

Stop taking sumatriptan and get emergency medical help right away if you have any of the following symptoms of a heart attack:
 • discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
 • severe lightheadedness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
 • pain or discomfort in your arms, back, neck, jaw, or stomach
 • shortness of breath with or without chest discomfort
 • breaking out in a cold sweat
 • nausea or vomiting
 • feeling lightheaded

Sumatriptan is not for people with risk factors for heart disease unless a heart exam is done and shows no problem. You have a higher risk for heart disease if you:
 • have high blood pressure
 • have high cholesterol levels
 • smoke
 • are overweight
 • have diabetes
 • have a family history of heart disease

What is sumatriptan?
 Sumatriptan is a prescription medicine used to treat acute migraine headaches with or without aura and acute cluster headaches in adults who have been diagnosed with migraine or cluster headaches.

Sumatriptan is not used to treat other types of headaches such as hemicrania (that make you unable to move on one side of your body) or basilar (rare form of migraine with aura) migraines.

Sumatriptan is not used to prevent or decrease the number of migraine or cluster headaches you have. It is not known if sumatriptan is safe and effective in children under 18 years of age.
Who should not take sumatriptan injection?
 Do not take sumatriptan injection if you have:
 • heart problems or a history of heart problems
 • narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
 • uncontrolled high blood pressure
 • severe liver problems
 • hemicrania migraines or basilar migraines. If you are not sure if you have these types of migraines, ask your healthcare provider.
 • had a stroke, transient ischemic attacks (TIAs), or problems with your blood circulation
 • taken any of the following medicines in the last 24 hours:

- almotriptan (AXERT®)
- eletriptan (RELPAX®)
- frovatriptan (FROVA®)
- naratriptan (AMERGE®)
- rizatriptan (MAXALT® MAXALT-MILT®)
- sumatriptan and naproxen (TREQMET®)
- sumatriptan succinate (SUNCTAM®)
- teliptan (TELPAK®)
- dihydroergotamine (D.H.E. 45® MIGRANAL®)

Ask your healthcare provider if you are not sure if your medicine is listed above.
 • an allergy to sumatriptan or any of the ingredients in sumatriptan injection. See the end of this leaflet for a complete list of ingredients in sumatriptan injection.

What should I tell my healthcare provider before taking sumatriptan injection?
 Before you take sumatriptan injection, tell your healthcare provider about all of your medical conditions, including if you:
 • have high blood pressure
 • have high cholesterol
 • have diabetes
 • smoke
 • are overweight
 • have heart problems or family history of heart problems or stroke
 • have kidney problems
 • have liver problems
 • have had epilepsy or seizures
 • are not using effective birth control
 • become pregnant while taking sumatriptan
 • are breastfeeding or plan to breastfeed. Sumatriptan passes into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take sumatriptan.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.
 Sumatriptan and certain other medicines can affect each other, causing serious side effects.
Especially tell your healthcare provider if you take anti-depressant medicines called:
 • selective serotonin reuptake inhibitors (SSRIs)
 • serotonin norepinephrine reuptake inhibitors (SNRIs)
 • tricyclic antidepressants (TCAs)
 • monoamine oxidase inhibitors (MAOIs)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.
 Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.
How should I take sumatriptan injection?
 • Certain people should take their first dose of sumatriptan injection in their healthcare provider's office or in another medical setting. Ask your healthcare provider if you should take your first dose in a medical setting.
 • Use sumatriptan injection exactly as your healthcare provider tells you to use it.
 • Your healthcare provider may change your dose. Do not change your dose without first talking with your healthcare provider.
 • For adults, the usual dose is a single injection given just below the skin.
 • You should give an injection as soon as the symptoms of your headache start, but it may be given at any time during a migraine or cluster headache attack.
 • If you did not get any relief after the first injection, do not give a second injection without first talking with your healthcare provider.
 • If your headache comes back or you only get some relief after your first injection, you can take a second injection 1 hour after the first injection, but not sooner.
 • Do not take more than 12 mg in a 24 hour period.
 • If you use too much sumatriptan injection, call your healthcare provider or go to the nearest hospital emergency room right away.
 • You should write down when you have headaches and when you take sumatriptan injection so you can talk with your healthcare provider about how sumatriptan injection is working for you.

What should I avoid while taking sumatriptan injection?
 Sumatriptan can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything where you need to be alert.

What are the possible side effects of sumatriptan injection?
 Sumatriptan may cause serious side effects. See "What is the most important information I should know about sumatriptan injection?"
 These serious side effects include:
 • changes in color or sensation in your fingers and toes (Raynaud's syndrome)
 • stomach and intestinal problems (gastrointestinal and colonic ischemic events). Symptoms of gastrointestinal and colonic ischemic events include:
 • sudden or severe stomach pain
 • stomach pain after meals
 • weight loss
 • nausea or vomiting
 • constipation or diarrhea
 • bloody diarrhea
 • fever
 • problems with blood circulation to your legs and feet (peripheral vascular ischemia). Symptoms of peripheral vascular ischemia include:
 • cramping and pain in your legs or feet
 • feeling of heaviness or tightness in your leg muscles
 • burning or aching pain in your feet or toes while resting
 • numbness, tingling, or weakness in your legs
 • cold feeling or color changes in 1 or both legs or feet
 • hives (bumpy bumps); swelling of your tongue, mouth, or throat
 • medication overdose headaches. Some people who use too many sumatriptan injections may have worse headaches (medication overdose headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with sumatriptan.
 • serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using sumatriptan injection, especially if sumatriptan injection is used with antidepressant medicines called SSRIs or SNRIs.

Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:
 • mental changes such as seeing things that are not there (hallucinations), agitation, or coma
 • fast heartbeat
 • changes in blood pressure
 • high body temperature
 • rigid muscles
 • trouble walking
 • seizures. Seizures have happened in people taking sumatriptan injection who have never had seizures before. Talk with your healthcare provider about your chance of having seizures while you take sumatriptan injection.

The most common side effects of sumatriptan injection include:
 • pain or redness at your injection site
 • tingling or numbness in your fingers or toes
 • dizziness
 • arm, leg, burning feeling to your face (flushing)
 • discomfort or stiffness in your neck
 • feeling weak, drowsy, or tired

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
 These are not all the possible side effects of sumatriptan injection. For more information, ask your healthcare provider or pharmacist.
 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store sumatriptan injection?
 • Store at 25°C (77°F); excursions permitted 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).
 • Store your medicine away from light.
 • Keep your medicine in the packaging or carrying case provided with it.

Keep sumatriptan injection and all medicines out of the reach of children.
 Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use sumatriptan injection for a condition for which it was not prescribed. Do not give sumatriptan injection to other people, even if they have the same symptoms you have. It may harm them.
 This Patient Information leaflet summarizes the most important information about sumatriptan injection. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about sumatriptan injection that is written for healthcare professionals.
 For more information, call 1-888-375-3784.

What are the ingredients in sumatriptan injection?
 Active ingredients: sumatriptan succinate USP
 Inactive ingredients: sodium chloride, water for injection

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SUMATRIPTAN INJECTION
INSTRUCTIONS FOR USE OF DISPOSABLE SUMATRIPTAN AUTOINJECTOR SYSTEM

Read this Patient Instructions for Use before you start to use Sumatriptan Autoinjector System. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about sumatriptan injection when you start taking it and at regular checkups



- Use the device immediately once the cap has been removed; it is advised not to postpone the injection.
- Keep the Sumatriptan Autoinjector System out of the reach of children.

Instructions for Use of Autoinjector Pen

Important things that you need to know
 This device is called an Autoinjector Pen. Here we use the shorter name 'pen'.

1. Read all of the instructions carefully before using this pen.
2. Follow these step-by-step instructions every time you use the pen.
3. Only use each pen once - do not try to use more than once.

If you have any further questions, ask your doctor or pharmacist.

A. ABOUT THE AUTOINJECTOR PEN

The parts of the pen are shown in this picture.



B. GETTING READY

Getting ready for the injection

1. Wash your hands
2. Choose an area with an adequate fatty tissue layer
3. Clean the skin area to be injected with alcohol or a new sterile swab

If you did not get any relief after the first injection, do not give a second injection without first talking with your healthcare provider.

If your headache comes back or you only get some relief after your first injection, you can take a second injection 1 hour after the first injection, but not sooner.

Do not take more than 12 mg in a 24 hour period.

If you use too much sumatriptan injection, call your healthcare provider or go to the nearest hospital emergency room right away.

You should write down when you have headaches and when you take sumatriptan injection so you can talk with your healthcare provider about how sumatriptan injection is working for you.

What should I avoid while taking sumatriptan injection?
 Sumatriptan can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything where you need to be alert.

What are the possible side effects of sumatriptan injection?
 Sumatriptan may cause serious side effects. See "What is the most important information I should know about sumatriptan injection?"

These serious side effects include:
 • changes in color or sensation in your fingers and toes (Raynaud's syndrome)
 • stomach and intestinal problems (gastrointestinal and colonic ischemic events). Symptoms of gastrointestinal and colonic ischemic events include:
 • sudden or severe stomach pain
 • stomach pain after meals
 • weight loss
 • nausea or vomiting
 • constipation or diarrhea
 • bloody diarrhea
 • fever
 • problems with blood circulation to your legs and feet (peripheral vascular ischemia). Symptoms of peripheral vascular ischemia include:
 • cramping and pain in your legs or feet
 • feeling of heaviness or tightness in your leg muscles
 • burning or aching pain in your feet or toes while resting
 • numbness, tingling, or weakness in your legs
 • cold feeling or color changes in 1 or both legs or feet
 • hives (bumpy bumps); swelling of your tongue, mouth, or throat
 • medication overdose headaches. Some people who use too many sumatriptan injections may have worse headaches (medication overdose headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with sumatriptan.
 • serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using sumatriptan injection, especially if sumatriptan injection is used with antidepressant medicines called SSRIs or SNRIs.

Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:
 • mental changes such as seeing things that are not there (hallucinations), agitation, or coma
 • fast heartbeat
 • changes in blood pressure
 • high body temperature
 • rigid muscles
 • trouble walking
 • seizures. Seizures have happened in people taking sumatriptan injection who have never had seizures before. Talk with your healthcare provider about your chance of having seizures while you take sumatriptan injection.

The most common side effects of sumatriptan injection include:
 • pain or redness at your injection site
 • tingling or numbness in your fingers or toes
 • dizziness
 • arm, leg, burning feeling to your face (flushing)
 • discomfort or stiffness in your neck
 • feeling weak, drowsy, or tired

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of sumatriptan injection. For more information, ask your healthcare provider or pharmacist.
 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store sumatriptan injection?
 • Store at 25°C (77°F); excursions permitted 15°C to 30°C (59°F to 86°F) (see USP Controlled Room Temperature).
 • Store your medicine away from light.
 • Keep your medicine in the packaging or carrying case provided with it.

Keep sumatriptan injection and all medicines out of the reach of children.
 Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use sumatriptan injection for a condition for which it was not prescribed. Do not give sumatriptan injection to other people, even if they have the same symptoms you have. It may harm them.
 This Patient Information leaflet summarizes the most important information about sumatriptan injection. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about sumatriptan injection that is written for healthcare professionals.
 For more information, call 1-888-375-3784.

What are the ingredients in sumatriptan injection?
 Active ingredients: sumatriptan succinate USP
 Inactive ingredients: sodium chloride, water for injection

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Getting the pen ready

4. Take the pen out of the package
5. Look in the medicine window on the pen

Before injection, to check that the liquid is clear.
 • If it is difficult to see what is in the window, hold the pen up to the light and check.
 • After injection, the plunger rod completely fills the medicine window.



If the plunger rod can be seen through the medicine window, the device is spent and cannot be used again.

6. Pull the cap off the pen
- Do not twist the cap
- Pull it straight off
- Keep the cap for step 7



Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of sumatriptan injection. For more information, ask your healthcare provider or pharmacist.
 Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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7. Look inside the cap, check that the gray needle cover is inside.

- Do not use the pen if the gray needle cover is not inside the cap



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8. Do not try to put the cap back
 - If you try to put it back, this will damage the needle

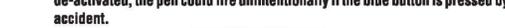
You are now ready to inject the medicine, go to step 9

C. INJECTING THE MEDICINE

9. Without pressing the blue button, push the pen firmly against your skin.

You will now see a small blue projection in the medicine window.

- As long as the blue circle is visible in the medicine window, the safety lock is de-activated; the pen could fire unintentionally if the blue button is pressed by accident.



Keep the pen pressed against your skin for the next steps

10. Do not attempt to re-engage the safety lock at any time.
11. Firmly press down the blue button on the top of the pen until it will not go further.

You will hear a loud click (this indicates that the injection has started)

- Keep pushing the pen against your skin



Without pressing the blue button, push the pen firmly against your skin.

- You will now see a small blue projection in the medicine window.
- As long as the blue circle is visible in the medicine window, the safety lock is de-activated; the pen could fire unintentionally if the blue button is pressed by accident.

Without pressing the blue button, push the pen firmly against your skin.

- You will now see a small blue projection in the medicine window.
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HIGHLIGHTS OF PRESCRIBING INFORMATION
 These highlights do not include all the information needed to use FONDAPARINUX SODIUM INJECTION safely and effectively. See full prescribing information for FONDAPARINUX SODIUM INJECTION.

FONDAPARINUX SODIUM INJECTION for subcutaneous use

Initial U.S. Approval: 2001

WARNING: SPINAL/EPIDURAL HEMATOMAS
 See full prescribing information for complete boxed warning.

Epidural or spinal hematomas may occur in patients who are anticoagulated with low molecular weight heparins (LMWH), heparinoids, or fondaparinux sodium and are receiving neuraxial anesthesia or undergoing spinal puncture.

These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- use of indwelling epidural catheters
- concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, or other anticoagulants
- a history of traumatic or repeated epidural or spinal puncture
- a history of spinal deformity or spinal surgery

Monitor patients frequently for signs and symptoms of neurologic impairment. If neurologic compromise is noted, urgent treatment is necessary.

Consider the benefit and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis. (See **Warnings and Precautions (5.5) and Drug Interactions (7.1)**.)

RECENT MAJOR CHANGES

Boxed Warning 07/2014
 Contraindications 09/2013
 Warnings and Precautions (5.5) 07/2014

INDICATIONS AND USAGE

Fondaparinux sodium injection is a Factor Xa inhibitor (anticoagulant) indicated for:

- Prophylaxis of deep vein thrombosis (DVT) in patients undergoing hip fracture surgery, including extended prophylaxis, hip replacement surgery, knee replacement surgery, or abdominal surgery. (1)
- Treatment of DVT of acute pulmonary embolism (PE) when administered in conjunction with warfarin. (1, 2, 3)

DOSE AND ADMINISTRATION

Prophylaxis of deep vein thrombosis: Fondaparinux sodium 2.5 mg subcutaneously once daily after hemostasis has been established. The initial dose should be given no earlier than 6 to 8 hours after surgery and continued for 5 to 9 days. For patients undergoing hip fracture surgery, extended prophylaxis up to 24 additional days is recommended. (2.1, 2.2)

Treatment of deep vein thrombosis and pulmonary embolism: Fondaparinux sodium 5 mg (body weight <50 kg), 7.5 mg (50 to 100 kg), or 10 mg (100 kg or more) subcutaneously once daily. Treatment should continue for at least 5 days until IIR or 2 to 3 achieved with warfarin sodium. (2.3)

Do not use as intramuscular injection. For subcutaneous use, do not mix with other injections or infusions.

FULL PRESCRIBING INFORMATION: CONTENTS

WARNING: SPINAL/EPIDURAL HEMATOMAS

1 INDICATIONS AND USAGE

2 DOSE AND ADMINISTRATION

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS

9 NURSING Mothers

FULL PRESCRIBING INFORMATION

WARNING: SPINAL/EPIDURAL HEMATOMAS

Epidural or spinal hematomas may occur in patients who are anticoagulated with low molecular weight heparins (LMWH), heparinoids, or fondaparinux sodium and are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- use of indwelling epidural catheters
- concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, or other anticoagulants
- a history of traumatic or repeated epidural or spinal puncture
- a history of spinal deformity or spinal surgery

Monitor patients frequently for signs and symptoms of neurologic impairment. If neurologic compromise is noted, urgent treatment is necessary.

Consider the benefit and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis. (See **Warnings and Precautions (5.5) and Drug Interactions (7.1)**.)

1 INDICATIONS AND USAGE

2.1 Deep Vein Thrombosis Prophylaxis Following Abdominal Surgery

Fondaparinux sodium injection is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients undergoing hip fracture surgery, including extended prophylaxis:

- in patients undergoing hip replacement surgery;
- in patients undergoing knee replacement surgery;
- in patients undergoing abdominal surgery who are at risk for thromboembolic complications.

2.2 Deep Vein Thrombosis Prophylaxis Following Hip Fracture Surgery

Fondaparinux sodium injection is indicated for the treatment of acute deep vein thrombosis when administered in conjunction with warfarin sodium when administered in conjunction with warfarin sodium.

2.3 Treatment of Acute Pulmonary Embolism

Fondaparinux sodium injection is indicated for the treatment of acute pulmonary embolism when administered in conjunction with warfarin sodium when administered in conjunction with warfarin sodium.

2.4 Hepatic Impairment

No dose adjustment is recommended in patients with mild to moderate hepatic impairment, based upon single-dose pharmacokinetic data. Pharmacokinetic data are not available for patients with severe hepatic impairment. Patients with hepatic impairment may be particularly vulnerable to bleeding during fondaparinux sodium therapy. Observe these patients closely for signs and symptoms of bleeding. (See **Clinical Pharmacology (12.4)**.)

2.5 Instructions for Use

Fondaparinux sodium injection is provided in a single-dose, pre-filled syringe affixed with an active needle protection system. Fondaparinux sodium injection is administered by subcutaneous injection. It must not be administered by intramuscular injection. Fondaparinux sodium injection is intended for use only as a single injection. Patients may self-inject only if their physician determines that it is appropriate and the patients are trained in subcutaneous injection technique.

Prior to administration, visually inspect fondaparinux sodium injection to ensure the solution is clear and free of particulate matter. The following instructions are specific to the Pre-filled Syringe injection system and may differ from instructions for other injection systems:

To avoid the loss of drug when using the pre-filled syringe, do not lift the air bubble from the syringe before the injection. Administration should be made at the full length of the syringe needle perpendicular into the skin fold held between the thumb and forefinger (Figure 2).

To administer fondaparinux sodium injection:

1. Wipe the surface of the injection site with an alcohol swab.
2. Remove the needle cap by pulling it straight off the syringe (Figure 1).
3. Discard the needle shield.

Do not try to remove the air bubbles from the syringe before giving the injection.

Place the tip of skin at the injection site between your thumb and forefinger and hold it throughout the injection time.

Hold the syringe with your thumb on the top of the plunger and keep your index and middle fingers on the finger-grips of the syringe barrel.

Place the syringe against your skin with the exposed needle.

Hold the full length of the syringe needle perpendicular into the skin fold held between the thumb and forefinger (Figure 2).

Push the plunger to the bottom of the syringe. This will ensure you have injected all the contents of the syringe.

Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

Figure 6

Figure 7

Figure 8

Figure 9

Figure 10

Figure 11

Figure 12

Figure 13

DOSE FORMS AND STRENGTHS

Single-dose, pre-filled syringes containing 2.5 mg, 5 mg, 7.5 mg, or 10 mg of fondaparinux (3)

CONTRAINDICATIONS

Fondaparinux sodium injection is contraindicated in the following conditions: (4)

- Severe renal impairment (creatinine clearance <30 mL/min) in prophylaxis or treatment of venous thromboembolism
- Thrombocytopenia can occur with administration of fondaparinux sodium. (5)
- Active major bleeding.
- Bacterial endocarditis.
- Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium.
- Body weight <50 kg (venous thromboembolism prophylaxis only).
- History of serious hypersensitivity reaction (e.g., angioedema, anaphylactoid/anaphylactic reactions) to fondaparinux sodium.

WARNINGS AND PRECAUTIONS

Use with caution in patients who have conditions or who are taking concomitant medications that increase risk of hemorrhage. (5-1)

Bleeding risk is increased in renal impairment and in patients with low body weight <50 kg (5.2, 5.3)

Thrombocytopenia can occur with administration of fondaparinux sodium. (5.4)

Periodic routine complete blood counts (including platelet counts), serum creatinine level, and stool occult blood tests are recommended (5.6)

ADVERSE REACTIONS

The most common adverse reactions associated with the use of fondaparinux sodium are bleeding complications. (See **Warnings and Precautions (5.1)**)

History of serious hypersensitivity reaction (e.g., angioedema, anaphylactoid/anaphylactic reactions) to fondaparinux sodium. (See **Warnings and Precautions (5.1)**)

Severe renal impairment (creatinine clearance <30 mL/min) in prophylaxis or treatment of venous thromboembolism. (See **Warnings and Precautions (5.1)**)

Active major bleeding. (See **Warnings and Precautions (5.2)**)

Bacterial endocarditis. (See **Warnings and Precautions (5.3)**)

Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium. (See **Warnings and Precautions (5.4)**)

Body weight <50 kg (venous thromboembolism prophylaxis only). (See **Warnings and Precautions (5.5)**)

History of serious hypersensitivity reaction (e.g., angioedema, anaphylactoid/anaphylactic reactions) to fondaparinux sodium. (See **Warnings and Precautions (5.6)**)

Periodic routine complete blood counts (including platelet counts), serum creatinine level, and stool occult blood tests are recommended (5.6)

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3 DOSAGE FORMS AND STRENGTHS

Single-dose, pre-filled syringes containing either 2.5 mg, 5 mg, 7.5 mg, or 10 mg of fondaparinux.

CONTRAINDICATIONS

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Promius Pharma

A Subsidiary of Dr. Reddy's Laboratories, Inc.

SB 486 Safe Needle Disposal Plan for 2016 – 2017

**Department of Resources Recycling and Recovery
(CalRecycle)**

01 July 2016

Background

The State of California has enacted two laws to address home generated sharps disposal. The first law (SB 1305), makes it illegal for any person in the state of California to dispose of home generated sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in an approved sharps container. This law became effective September 1, 2008. In 2009, California enacted (SB 486) which requires any pharmaceutical manufacturer that sells or distributes medication that is self-injected at home through the use of hypodermic needles and other similar devices to submit to the board, or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of waste devices. This plan is due on July 1, 2010 and annually thereafter.

Promius Pharma Self-Injectable Products Subject To These Regulations in California

Promius Pharma currently markets, distributes, and/or sells one self-injectable product in the State of California. The name of this product is **ZEMBRACE™ SymTouch™ (sumatriptan injection) 3 mg/0.5 mL**.

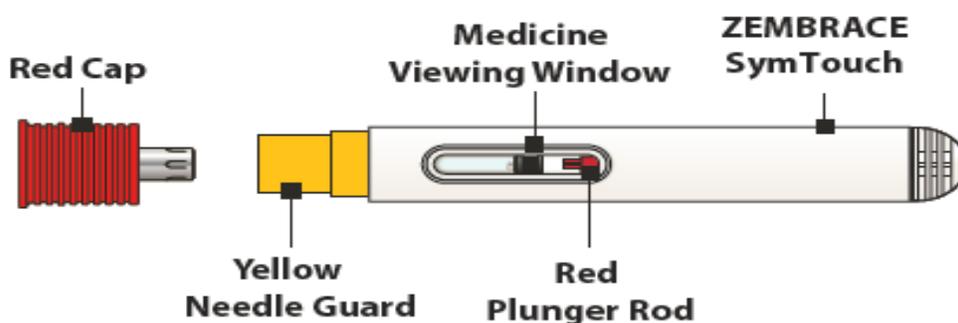
Promius Pharma supports safe collection and proper disposal of home generated sharps

Promius Pharma supports appropriate and safe disposal of home-generated waste sharps. Patient safety and needle stick injury prevention were given serious consideration as the above-mentioned products were being developed.

During the development of ZEMBRACE™ SymTouch™ (sumatriptan injection) 3 mg/0.5 mL Promius Pharma employed safe needle technology in order to protect patients and those assisting in the disposal of waste sharps. Specifically, ZEMBRACE™ SymTouch™ (sumatriptan injection) 3 mg/0.5 mL uses a 29 gauge needle that is 0.5mm (1/4 inch) long and has a needle shield which covers the needle and locks after the injection. The patient is then instructed to recap the device for disposal. The steps for use of the auto-injector are described in the ZEMBRACE™ SymTouch™ (sumatriptan injection) 3 mg/0.5 mL Patient Information and Instructions for Use (IFU) leaflets.

ZEMBRACE™ SymTouch™ (sumatriptan injection) 3 mg/0.5 mL

The parts of the auto-injector are shown in this picture

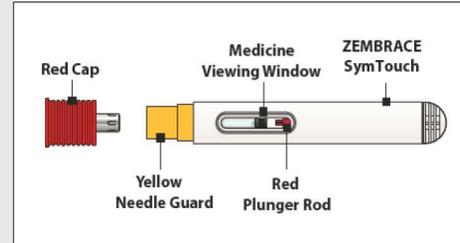


Read this Instructions for Use before you start to use ZEMBRACE™ SymTouch™. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about ZEMBRACE SymTouch when you start taking it and at regular checkups.

The ZEMBRACE SymTouch Autoinjector is a single-use, pre-filled injection device with the exact dose you need. The device should be used only 1 time and then discarded.

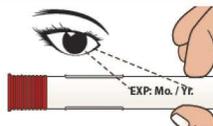
⚠ Important Precautions

- Keep out of reach of children.
- Do not use after the expiration date has passed.**
- Do not store or expose to high temperatures.**
- Do not freeze.**
- Do not remove the Red Cap until you are ready to inject.**
- Do not use if dropped after removing the Red Cap.**
- Do not put or press thumb, fingers or hand over the Yellow Needle Guard.**



Step 1 - Inspect Autoinjector and Gather Supplies

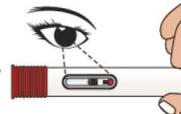
- ▶ 1A - Remove Autoinjector from the carton
- ▶ 1B - Check the Expiration Date on the Autoinjector
- ▶ 1C - Inspect the medicine through the Medicine Viewing Window
- ▶ 1D - Gather the following supplies



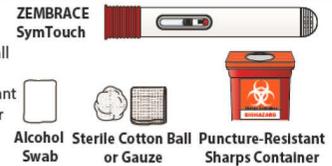
Do not use if the expiration date has passed.

Inspect the appearance of ZEMBRACE SymTouch Autoinjector medicine through the medicine viewing window. It must be a clear, colorless to pale yellow solution.

Do not inject the medicine if the solution looks discolored or cloudy or contains lumps, flakes, or particles.



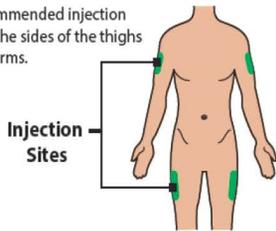
- 1. Autoinjector
- 2. Alcohol Swab
- 3. Sterile Cotton Ball or Gauze
- 4. Puncture-Resistant Sharps Container



Step 2 - Choose and Prepare Your Injection Site

- ▶ 2A - Choose your injection site
- ▶ 2B - Clean the injection site with an alcohol swab
- ▶ 2C - Remove the Red Cap

The recommended injection sites are the sides of the thighs and the arms.

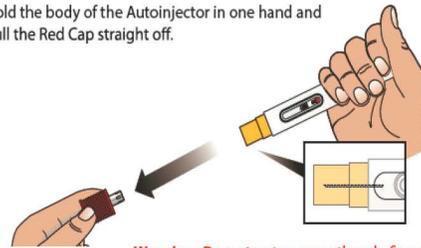


Caution: Do not inject where your skin is scarred, bruised, tender, red or near any open wound.



Do not touch injection site area after cleaning.

Hold the body of the Autoinjector in one hand and pull the Red Cap straight off.



Warning: Do not put or press thumb, fingers or hand over the Yellow Needle Guard, doing so may result in a needle stick injury.

Step 3 - Inject the Medicine

- ▶ 3A - Place Autoinjector straight on your injection site
- ▶ 3B - Perform Injection
- ▶ 3C - Remove Autoinjector from skin

Place the Autoinjector straight on your injection site (90 degrees) with the Yellow Needle Guard end gently pressed against your skin.



Press and hold the Autoinjector down against your skin. You will hear the first "Click 1" as the injection starts. Continue to hold the device down until you hear the second "Click 2."

Wait 5 seconds before you remove the Autoinjector!



HOLD!



WAIT!

CONTINUE TO HOLD DOWN AND SLOWLY COUNT TO 5.

⌚ 1...2...3...4...5

Remove the Autoinjector by lifting it straight away from your skin. The Yellow Needle Guard will drop down and lock over the needle.

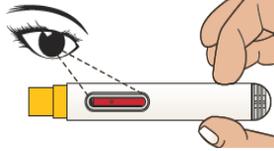


Important: To receive your full dose, always hold the Autoinjector down on your injection site for additional time after you hear the second click. This allows all of the medicine to be delivered.

Step 4 - Confirm Injection and Dispose the Autoinjector

▶ 4A - Confirm Red Color in Medicine Viewing Window

Look to confirm that the Red Plunger Rod has filled the Medicine Viewing Window. This means you received the full dose.



Caution: Call your healthcare provider if the Red Plunger Rod has not filled the Medicine Viewing Window. This may mean that only a partial dose was delivered.

Do not try to reuse the Autoinjector.

▶ 4B - Disposal of the Autoinjector

Put your used Autoinjector, caps, needles, and sharps in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash. Do not recycle your used sharps disposal container.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is made of a heavy-duty plastic; can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out; upright and stable during use; leak-resistant; and properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

If needed, make sure you get a refill of your Autoinjector.



▶ 4C - Treat Injection Site

Treat the injection site with a cotton ball, gauze pad or bandage, as needed.

Do not rub the injection site.

ZEMBRACE SymTouch are registered trademarks of Dr. Reddy's Laboratories, Ltd.

PROMIUS PHARMA

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Month Year

Patient Education Materials:

Patients who self-inject Promius Pharma products at home should receive instructions from their healthcare providers on how to use these products properly. The full prescribing information is available to healthcare providers. Patients should read the Patient Information and the Instructions for Use (IFU) leaflets that come with each product before they start taking each product and each time the prescription is refilled as there may be new information.

Promius Pharma has also created a patient specific website for ZEMBRACE™ SymTouch™ (sumatriptan injection) 3 mg/0.5 mL at www.zembrace.com. This website provides patients with the most important information they need to know from Promius Pharma. The information on this website does not take the place of talking with the patient's healthcare provider about the medical conditions or treatments.

Patients and caregivers can also contact Promius Pharma at 1-888-966-8766 with questions about this product.

Disposal:

Patients and consumers have several options available to them to safely dispose sharps waste. Patients may visit the CalRecycle website <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm> to become familiar with all disposal options available and select the option that is most convenient. Below are disposal options detailed on the California CalRecycle website.

- Patients may use the Disposal Directory (FacIT) for Sharps and Medication (via link <http://www.calrecycle.ca.gov/facit/facility/search.aspx>). In this directory, you may locate facilities that collect sharps for disposal near to where you live or work. Collection programs include:
 - **Pharmacies.** Some drug stores take back their customers' needles, especially in small quantities.
 - **Hospitals.** Hospitals may take back sharps from patients using regular outpatient services.
 - **Local Household Hazardous Waste Programs.** Call your local household hazardous waste agency and ask if they collect needles (sharps) at their collection facilities or on household hazardous waste days. You can also look for this information here:
 - Your local white pages' government section may list your city's or county's household hazardous waste department.

- Visit the <http://www.earth911.com/recycling-guide/how-to-recycle-medical-sharps/> website or call 1-800-CLEANUP (1-800-253-2687), a service of Earth 911.
- **Local Jurisdiction Sharps Collection Programs.** A file showing a sampling of local jurisdictions' sharps collection programs containing contacts, e-mail addresses, program summaries, and outreach materials may be found at <http://www.calrecycle.ca.gov/homehazwaste/sharps/LocalProgram.pdf> this spreadsheet could help jurisdictions that don't currently have collection programs to set up their own sharps collection program.
- **Needle Destruction Devices.** The U.S. Food and Drug Administration (FDA) currently only lists the "Disintegrator" as a needle destruction device approved for use by self-injectors.
- **Mail-Back Service.** A list of sharps waste mail-back services authorized for use in California is available from the California Department of Public Health (CDPH) is available at <https://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/SharpsMailBackList.pdf>
- **Sharps Containers.** The California Department of Public Health Medical Waste Management Program is recommending the use of sharps containers approved by the FDA. After accessing the FDA website www.fda.gov, type "sharps" in the search box. The container names will display alphabetically.

For More Information

Stay informed about the latest developments in CalRecycle's efforts to promote safe disposal of sharps waste.

- **Listserv:** To receive periodic information about sharps, subscribe to the Sharps and Medication Disposal Listserv at <http://www.calrecycle.ca.gov/listservs/Subscribe.aspx?ListID=73>
- **Contact:** Please contact <http://www.calrecycle.ca.gov/homehazwaste/sharps/> for questions or more information.

Company Contact Information:

If you would like assistance from Promius Pharma in identifying your disposal options, please contact a Promius Pharma representative at 1-888-966-8766. Representatives are available to assist patients with questions about each of these products, including product administration and medical waste disposal.

Promius Pharma remains committed to help facilitate the safe disposal of its products and will continue to evaluate feedback and make modifications to this plan as needed.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ZEMBRACE™ SymTouch™ safely and effectively. See full prescribing information for ZEMBRACE™ SymTouch™.

ZEMBRACE™ SymTouch™ (sumatriptan succinate) Injection, for subcutaneous use
Initial U.S. Approval: 1992

INDICATIONS AND USAGE

ZEMBRACE SymTouch is a serotonin (5-HT_{1B/1D}) receptor agonist (triptan) indicated for:

- Acute treatment of migraine with or without aura in adults (1)

Limitations of Use:

- Use only if a clear diagnosis of migraine has been established. (1)
- Not indicated for the prophylactic therapy of migraine. (1)

DOSAGE AND ADMINISTRATION

- For subcutaneous use only. (2.1)
- Acute treatment of migraine: 3 mg Single dose. (2.1)
- Maximum dose in a 24-hour period: 12 mg. Separate doses by at least 1 hour. (2.1)

DOSAGE FORMS AND STRENGTHS

- Injection: 3-mg prefilled, ready-to use, single-dose disposable autoinjector. (3).

CONTRAINDICATIONS

- History of coronary artery disease or coronary vasospasm (4)
- Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders (4)
- History of stroke, transient ischemic attack, or hemiplegic or basilar migraine (4)
- Peripheral vascular disease (4)
- Ischemic bowel disease (4)
- Uncontrolled hypertension (4)
- Recent (within 24 hours) use of another 5-HT₁ agonist (e.g., another triptan) or of an ergotamine-containing medication (4)
- Concurrent or recent (past 2 weeks) use of monoamine oxidase-A inhibitor (4)

- Hypersensitivity to sumatriptan (angioedema and anaphylaxis seen) (4)
- Severe hepatic impairment (4)

WARNINGS AND PRECAUTIONS

- Myocardial ischemia/infarction and Prinzmetal's angina: Perform cardiac evaluation in patients with multiple cardiovascular risk factors. (5.1)
- Arrhythmias: Discontinue ZEMBRACE SymTouch if occurs. (5.2)
- Chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Generally not associated with myocardial ischemia; evaluate for coronary artery disease in patients at high risk. (5.3)
- Cerebral hemorrhage, subarachnoid hemorrhage, and stroke: Discontinue ZEMBRACE SymTouch if occurs. (5.4)
- Gastrointestinal ischemia and reactions, peripheral vasospastic reactions: Discontinue ZEMBRACE SymTouch if occurs. (5.5)
- Medication overuse headache: Detoxification may be necessary. (5.6)
- Serotonin syndrome: Discontinue ZEMBRACE SymTouch if occurs. (5.7)
- Seizures: Use with caution in patients with epilepsy or a lowered seizure threshold. (5.10)

ADVERSE REACTIONS

Most common adverse reactions (≥5% and > placebo) were injection site reactions, tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, flushing, feeling of tightness, and numbness. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Promius Pharma, LLC. at 1-888-966-8766 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm (8.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 1/2016

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ZEMBRACE SymTouch is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

- Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with ZEMBRACE SymTouch, reconsider the diagnosis before ZEMBRACE SymTouch is administered to treat any subsequent attacks.
- ZEMBRACE SymTouch injection is not indicated for the prevention of migraine attacks.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information

The recommended dose of ZEMBRACE SymTouch is 3 mg injected subcutaneously.

The maximum cumulative dose that may be given in 24 hours is 12 mg; one 3 mg injection may be given up to four times a day with each injection at least 1 hour apart.

2.2 Administration Using ZEMBRACE SymTouch

ZEMBRACE SymTouch is available as a prefilled, ready-to-use, single dose, disposable auto-injector containing 3 mg sumatriptan. With ZEMBRACE SymTouch, the needle penetrates approximately ¼ inch (6 mm). The injection is intended to be given subcutaneously. Do not administer by any other route. Instruct patients on the proper use of ZEMBRACE SymTouch and direct them to use injection sites with an adequate skin and subcutaneous thickness to accommodate the length of the needle.

3 DOSAGE FORMS AND STRENGTHS

Injection: 3 mg sumatriptan in 0.5 mL prefilled, ready-to-use, single dose, disposable auto-injector.

4 CONTRAINDICATIONS

ZEMBRACE SymTouch injection is contraindicated in patients with:

- Ischemic coronary artery disease (CAD) (angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetal's angina [*see Warnings and Precautions (5.1)*].
- Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders [*see Warnings and Precautions (5.2)*].

- History of stroke or transient ischemic attack (TIA) or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke [see *Warnings and Precautions (5.4)*].
- Peripheral vascular disease [see *Warnings and Precautions (5.5)*].
- Ischemic bowel disease [see *Warnings and Precautions (5.5)*].
- Uncontrolled hypertension [see *Warnings and Precautions (5.8)*].
- Recent (i.e., within 24 hours) use of ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), or another 5-hydroxytryptamine₁ (5-HT₁) agonist [see *Drug Interactions (7.1, 7.3)*].
- Concurrent administration of an MAO-A inhibitor or recent (within 2 weeks) use of an MAO-A inhibitor [see *Drug Interactions (7.2)* and *Clinical Pharmacology (12.3)*].
- Known hypersensitivity to sumatriptan (angioedema and anaphylaxis seen) [see *Warnings and Precautions (5.9)*].
- Severe hepatic impairment [see *Clinical Pharmacology (12.3)*].

5 WARNINGS AND PRECAUTIONS

5.1 Myocardial Ischemia, Myocardial Infarction, and Prinzmetal's Angina

The use of ZEMBRACE SymTouch injection is contraindicated in patients with ischemic or vasospastic CAD. There have been rare reports of serious cardiac adverse reactions, including acute myocardial infarction, occurring within a few hours following administration of sumatriptan injection. Some of these reactions occurred in patients without known CAD. 5-HT₁ agonists, including ZEMBRACE SymTouch injection, may cause coronary artery vasospasm (Prinzmetal's angina), even in patients without a history of CAD.

Perform a cardiovascular evaluation in triptan-naïve patients who have multiple cardiovascular risk factors (e.g., increased age, diabetes, hypertension, smoking, obesity, strong family history of CAD) prior to receiving ZEMBRACE SymTouch injection. If there is evidence of CAD or coronary artery vasospasm, ZEMBRACE SymTouch injection is contraindicated. For patients with multiple cardiovascular risk factors who have a negative cardiovascular evaluation, consider administering the first dose of ZEMBRACE SymTouch injection in a medically supervised setting and performing an electrocardiogram (ECG) immediately following ZEMBRACE SymTouch injection. For such patients, consider periodic cardiovascular evaluation in intermittent long-term users of ZEMBRACE SymTouch injection.

5.2 Arrhythmias

Life-threatening disturbances of cardiac rhythm, including ventricular tachycardia and ventricular fibrillation leading to death, have been reported within a few hours following the administration of 5-HT₁ agonists. Discontinue ZEMBRACE SymTouch injection if these

disturbances occur. ZEMBRACE SymTouch injection is contraindicated in patients with Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders.

5.3 Chest, Throat, Neck, and/or Jaw Pain/Tightness/Pressure

Sensations of tightness, pain, pressure, and heaviness in the precordium, throat, neck, and jaw commonly occur after treatment with sumatriptan injection and are usually non-cardiac in origin. However, perform a cardiac evaluation if these patients are at high cardiac risk. The use of ZEMBRACE SymTouch injection is contraindicated in patients shown to have CAD and those with Prinzmetal's variant angina.

5.4 Cerebrovascular Events

Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-HT₁ agonists, and some have resulted in fatalities. In a number of cases, it appears possible that the cerebrovascular events were primary, the 5-HT₁ agonist having been administered in the incorrect belief that the symptoms experienced were a consequence of migraine when they were not. Also, patients with migraine may be at increased risk of certain cerebrovascular events (e.g., stroke, hemorrhage, TIA). Discontinue ZEMBRACE SymTouch injection if a cerebrovascular event occurs.

Before treating headaches in patients not previously diagnosed with migraine or in patients who present with atypical symptoms, exclude other potentially serious neurological conditions. ZEMBRACE SymTouch injection is contraindicated in patients with a history of stroke or TIA.

5.5 Other Vasospasm Reactions

ZEMBRACE SymTouch injection may cause non-coronary vasospastic reactions, such as peripheral vascular ischemia, gastrointestinal vascular ischemia and infarction (presenting with abdominal pain and bloody diarrhea), splenic infarction, and Raynaud's syndrome. In patients who experience symptoms or signs suggestive of non-coronary vasospasm reaction following the use of any 5-HT₁ agonist, rule out a vasospastic reaction before receiving additional ZEMBRACE SymTouch injections.

Reports of transient and permanent blindness and significant partial vision loss have been reported with the use of 5-HT₁ agonists. Since visual disorders may be part of a migraine attack, a causal relationship between these events and the use of 5-HT₁ agonists have not been clearly established.

5.6 Medication Overuse Headache

Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, combination of these drugs for 10 or more days per month) may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches, or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs, and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

5.7 Serotonin Syndrome

Serotonin syndrome may occur with ZEMBRACE SymTouch injection, particularly during co-administration with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and MAO inhibitors [see *Drug Interactions (7.4)*]. Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination), and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). The onset of symptoms usually occurs within minutes to hours of receiving a new or a greater dose of a serotonergic medication. Discontinue ZEMBRACE SymTouch injection if serotonin syndrome is suspected.

5.8 Increase in Blood Pressure

Significant elevation in blood pressure, including hypertensive crisis with acute impairment of organ systems, has been reported on rare occasions in patients treated with 5-HT₁ agonists, including patients without a history of hypertension. Monitor blood pressure in patients treated with ZEMBRACE SymTouch. ZEMBRACE SymTouch injection is contraindicated in patients with uncontrolled hypertension.

5.9 Anaphylactic Reactions

Anaphylactic reactions have occurred in patients receiving sumatriptan. Such reactions can be life threatening or fatal. In general, anaphylactic reactions to drugs are more likely to occur in individuals with a history of sensitivity to multiple allergens. ZEMBRACE SymTouch injection is contraindicated in patients with a history of hypersensitivity reaction to sumatriptan.

5.10 Seizures

Seizures have been reported following administration of sumatriptan. Some have occurred in patients with either a history of seizures or concurrent conditions predisposing to seizures. There are also reports in patients where no such predisposing factors are apparent. ZEMBRACE SymTouch injection should be used with caution in patients with a history of epilepsy or conditions associated with a lowered seizure threshold.

6 ADVERSE REACTIONS

The following serious adverse reactions are described below and elsewhere in the labeling:

- Myocardial ischemia, myocardial infarction, and Prinzmetal's angina [see *Warnings and Precautions (5.1)*]
- Arrhythmias [see *Warnings and Precautions (5.2)*]
- Chest, throat, neck, and/or jaw pain/tightness/pressure [see *Warnings and Precautions (5.3)*]
- Cerebrovascular events [see *Warnings and Precautions (5.4)*]

- Other vasospasm reactions [*see Warnings and Precautions (5.5)*]
- Medication overuse headache [*see Warnings and Precautions (5.6)*]
- Serotonin syndrome [*see Warnings and Precautions (5.7)*]
- Increase in blood pressure [*see Warnings and Precautions (5.8)*]
- Hypersensitivity reactions [*see Contraindications (4), Warnings and Precautions (5.9)*]
- Seizures [*see Warnings and Precautions (5.10)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Migraine Headache: [Table 1](#) lists adverse reactions that occurred in 2 US placebo-controlled clinical trials in migraine subjects (Studies 2 and 3), following either a single 6-mg dose of sumatriptan injection or placebo. Only reactions that occurred at a frequency of 2% or more in groups treated with sumatriptan injection 6 mg and that occurred at a frequency greater than the placebo group are included in [Table 1](#).

Table 1: Adverse Reactions in Pooled Placebo-Controlled Trials in Patients with Migraine (Studies 2 and 3)

Adverse Reaction	Percent of Subjects Reporting	
	Sumatriptan Injection 6 mg Subcutaneous (n = 547)	Placebo (n = 370)
Atypical sensations	42	9
Tingling	14	3
Warm/hot sensation	11	4
Burning sensation	7	<1
Feeling of heaviness	7	1
Pressure sensation	7	2
Feeling of tightness	5	<1
Numbness	5	2
Feeling strange	2	<1
Tight feeling in head	2	<1
Cardiovascular		
Flushing	7	2
Chest discomfort	5	1
Tightness in chest	3	<1
Pressure in chest	2	<1
Ear, nose, and throat		
Throat discomfort	3	<1
Discomfort: nasal cavity/sinuses	2	<1
Injection site reaction ^a	59	24
Miscellaneous		
Jaw discomfort	2	0
Musculoskeletal		
Weakness	5	<1
Neck pain/stiffness	5	<1
Myalgia	2	<1
Neurological		
Dizziness/vertigo	12	4
Drowsiness/sedation	3	2
Headache	2	<1
Skin		
Sweating	2	1

^a Includes injection site pain, stinging/burning, swelling, erythema, bruising, bleeding.

The incidence of adverse reactions in controlled clinical trials was not affected by gender or age of the patients. There were insufficient data to assess the impact of race on the incidence of adverse reactions.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of sumatriptan tablets, sumatriptan nasal spray, and sumatriptan injection. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Cardiovascular

Hypotension, palpitations

Neurological

Dystonia, tremor

7 DRUG INTERACTIONS

7.1 Ergot-Containing Drugs

Ergot-containing drugs have been reported to cause prolonged vasospastic reactions. Because these effects may be additive, use of ergotamine-containing or ergot-type medications (like dihydroergotamine or methysergide) and ZEMBRACE SymTouch within 24 hours of each other is contraindicated.

7.2 Monoamine Oxidase-A Inhibitors

MAO-A inhibitors increase systemic exposure by 2-fold. Therefore, the use of ZEMBRACE SymTouch injection in patients receiving MAO-A inhibitors is contraindicated [*see Clinical Pharmacology (12.3)*].

7.3 Other 5-HT₁ Agonists

Because their vasospastic effects may be additive, coadministration of ZEMBRACE SymTouch injection and other 5-HT₁ agonists (e.g., triptans) within 24 hours of each other is contraindicated.

7.4 Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors and Serotonin Syndrome

Cases of serotonin syndrome have been reported during coadministration of triptans and SSRIs, SNRIs, TCAs, and MAO inhibitors [*see Warnings and Precautions (5.7)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: There are no adequate and well-controlled trials of sumatriptan injection in pregnant women. In developmental toxicity studies in rats and rabbits, oral administration of sumatriptan to pregnant animals was associated with embryoletality, fetal abnormalities, and pup mortality. When administered by the intravenous route to pregnant rabbits, sumatriptan was

embryolethal. ZEMBRACE SymTouch injection should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Oral administration of sumatriptan to pregnant rats during the period of organogenesis resulted in an increased incidence of fetal blood vessel (cervicothoracic and umbilical) abnormalities. The highest no-effect dose for embryofetal developmental toxicity in rats was 60 mg/kg/day. Oral administration of sumatriptan to pregnant rabbits during the period of organogenesis resulted in increased incidences of embryolethality and fetal cervicothoracic vascular and skeletal abnormalities. Intravenous administration of sumatriptan to pregnant rabbits during the period of organogenesis resulted in an increased incidence of embryolethality. The highest oral and intravenous no-effect doses for developmental toxicity in rabbits were 15 and 0.75 mg/kg/day, respectively.

Oral administration of sumatriptan to rats prior to and throughout gestation resulted in embryofetal toxicity (decreased body weight, decreased ossification, increased incidence of skeletal abnormalities). The highest no-effect dose was 50 mg/kg/day. In offspring of pregnant rats treated orally with sumatriptan during organogenesis, there was a decrease in pup survival. The highest no-effect dose for this effect was 60 mg/kg/day. Oral treatment of pregnant rats with sumatriptan during the latter part of gestation and throughout lactation resulted in a decrease in pup survival. The highest no-effect dose for this finding was 100 mg/kg/day.

8.3 Nursing Mothers

Sumatriptan is excreted in human milk following subcutaneous administration. Infant exposure to sumatriptan can be minimized by avoiding breastfeeding for 12 hours after treatment with ZEMBRACE SymTouch injection.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. ZEMBRACE SymTouch injection is not recommended for use in patients younger than 18 years of age.

Two controlled clinical trials evaluated sumatriptan nasal spray (5 to 20 mg) in 1,248 pediatric migraineurs 12 to 17 years of age who treated a single attack. The trials did not establish the efficacy of sumatriptan nasal spray compared with placebo in the treatment of migraine in pediatric patients. Adverse reactions observed in these clinical trials were similar in nature to those reported in clinical trials in adults.

Five controlled clinical trials (2 single-attack trials, 3 multiple-attack trials) evaluating oral sumatriptan (25 to 100 mg) in pediatric subjects 12 to 17 years of age enrolled a total of 701 pediatric migraineurs. These trials did not establish the efficacy of oral sumatriptan compared with placebo in the treatment of migraine in pediatric patients. Adverse reactions observed in these clinical trials were similar in nature to those reported in clinical trials in adults. The frequency of all adverse reactions in these patients appeared to be both dose- and age-dependent, with younger patients reporting reactions more commonly than older pediatric patients.

Postmarketing experience documents that serious adverse reactions have occurred in the pediatric population after use of subcutaneous, oral, and/or intranasal sumatriptan. These reports include reactions similar in nature to those reported rarely in adults, including stroke, visual loss, and

death. A myocardial infarction has been reported in a 14-year-old male following the use of oral sumatriptan; clinical signs occurred within 1 day of drug administration. Clinical data to determine the frequency of serious adverse reactions in pediatric patients who might receive subcutaneous, oral, or intranasal SUMATRIPTAN are not presently available.

8.5 Geriatric Use

Clinical trials of sumatriptan injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

A cardiovascular evaluation is recommended for geriatric patients who have other cardiovascular risk factors (e.g., diabetes, hypertension, smoking, obesity, strong family history of CAD) prior to receiving ZEMBRACE SymTouch injection [see *Warnings and Precautions (5.1)*].

10 OVERDOSAGE

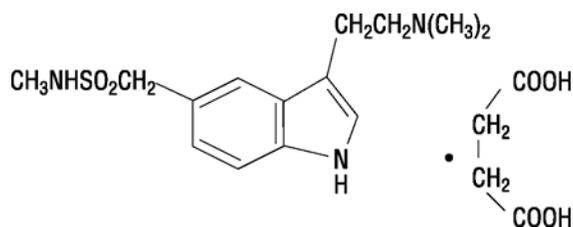
Coronary vasospasm was observed after intravenous administration of sumatriptan injection [see *Contraindications (4)*]. Overdoses would be expected from animal data (dogs at 0.1 g/kg, rats at 2 g/kg) to possibly cause convulsions, tremor, inactivity, erythema of the extremities, reduced respiratory rate, cyanosis, ataxia, mydriasis, injection site reactions (desquamation, hair loss, and scab formation), and paralysis.

The elimination half-life of sumatriptan is about 2 hours [see *Clinical Pharmacology (12.3)*], and therefore monitoring of patients after overdose with ZEMBRACE SymTouch injection should continue for at least 10 hours or while symptoms or signs persist.

It is unknown what effect hemodialysis or peritoneal dialysis has on the serum concentrations of sumatriptan.

11 DESCRIPTION

ZEMBRACE SymTouch injection contains sumatriptan succinate, a selective 5-HT_{1B/1D} receptor agonist. Sumatriptan succinate is chemically designated as 3-[2-(dimethylamino) ethyl]-N-methyl-indole-5-methanesulfonamide succinate (1:1), and it has the following structure:



The empirical formula is $C_{14}H_{21}N_3O_2S \cdot C_4H_6O_4$, representing a molecular weight of 413.5. Sumatriptan succinate is a white to off-white powder that is readily soluble in water and in saline.

ZEMBRACE SymTouch is a clear, colorless to pale yellow, sterile, nonpyrogenic solution for subcutaneous injection. Each 0.5 mL of ZEMBRACE SymTouch contains 4.2 mg of sumatriptan succinate equivalent to 3-mg of sumatriptan (base) and 4.15 mg of sodium chloride, USP in Water for Injection, USP.

The pH range of solution is approximately 4.2 to 5.3 and the osmolality of injection is approximately 291 mOsmol (275 to 315 mOsmol).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Sumatriptan binds with high affinity to human cloned 5-HT_{1B/1D} receptors. Sumatriptan presumably exerts its therapeutic effects in the treatment of migraine headache through agonist effects at the 5-HT_{1B/1D} receptors on intracranial blood vessels and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

12.2 Pharmacodynamics

Blood Pressure: Significant elevation in blood pressure, including hypertensive crisis, has been reported in patients with and without a history of hypertension [*see Warnings and Precautions (5.8)*].

Peripheral (Small) Arteries: In healthy volunteers (N = 18), a trial evaluating the effects of sumatriptan on peripheral (small vessel) arterial reactivity failed to detect a clinically significant increase in peripheral resistance.

Heart Rate: Transient increases in blood pressure observed in some subjects in clinical trials carried out during sumatriptan's development as a treatment for migraine were not accompanied by any clinically significant changes in heart rate.

12.3 Pharmacokinetics

After a single 3-mg dose, ZEMBRACE SymTouch was bioequivalent to IMITREX subcutaneous injection.

Absorption and Bioavailability: The bioavailability of sumatriptan via subcutaneous site injection to 18 healthy male subjects was $97\% \pm 16\%$ of that obtained following intravenous injection.

After a single 6-mg subcutaneous manual injection into the deltoid area of the arm in 18 healthy males (age: 24 ± 6 years, weight: 70 kg), the maximum serum concentration (C_{max}) of sumatriptan was (mean \pm standard deviation) 74 ± 15 ng/mL and the time to peak concentration (T_{max}) was 12 minutes after injection (range: 5 to 20 minutes). In this trial, the same dose injected subcutaneously in the thigh gave a C_{max} of 61 ± 15 ng/mL by manual injection versus

52 ±15 ng/mL by auto-injector techniques. The T_{max} or amount absorbed was not significantly altered by either the site or technique of injection.

Distribution: Protein binding, determined by equilibrium dialysis over the concentration range of 10 to 1,000 ng/mL, is low, approximately 14% to 21%. The effect of sumatriptan on the protein binding of other drugs has not been evaluated.

Following a 6-mg subcutaneous injection into the deltoid area of the arm in 9 males (mean age: 33 years, mean weight: 77 kg) the volume of distribution central compartment of sumatriptan was 50 ± 8 liters and the distribution half-life was 15 ± 2 minutes.

Metabolism: In vitro studies with human microsomes suggest that sumatriptan is metabolized by MAO, predominantly the A isoenzyme. Most of a radiolabeled dose of sumatriptan excreted in the urine is the major metabolite indole acetic acid (IAA) or the IAA glucuronide, both of which are inactive.

Elimination: After a single 6-mg subcutaneous dose, 22% ± 4% was excreted in the urine as unchanged sumatriptan and 38% ± 7% as the IAA metabolite.

Following a 6-mg subcutaneous injection into the deltoid area of the arm, the systemic clearance of sumatriptan was 1,194 ± 149 mL/min and the terminal half-life was 115 ± 19 minutes.

Specific Populations:

Age: The pharmacokinetics of sumatriptan in the elderly (mean age: 72 years, 2 males and 4 females) and in subjects with migraine (mean age: 38 years, 25 males and 155 females) were similar to that in healthy male subjects (mean age: 30 years).

Hepatic Impairment: The effect of mild to moderate hepatic disease on the pharmacokinetics of subcutaneously administered sumatriptan has been evaluated. There were no significant differences in the pharmacokinetics of subcutaneously administered sumatriptan in moderately hepatically impaired subjects compared with healthy controls. The pharmacokinetics of subcutaneously administered sumatriptan in patients with severe hepatic impairment has not been studied. The use of ZEMBRACE SymTouch injection in this population is contraindicated [see *Contraindications (4)*].

Race: The systemic clearance and C_{max} of subcutaneous sumatriptan were similar in black (n = 34) and Caucasian (n = 38) healthy male subjects.

Drug Interaction Studies:

Monoamine Oxidase-A Inhibitors: In a trial of 14 healthy females, pretreatment with an MAO-A inhibitor decreased the clearance of sumatriptan, resulting in a 2-fold increase in the area under the sumatriptan plasma concentration-time curve (AUC), corresponding to a 40% increase in elimination half-life [see *Contraindications (4)*].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In carcinogenicity studies in mouse and rat, sumatriptan was administered orally for 78 weeks and 104 weeks, respectively, at doses up to 160 mg/kg/day (the highest dose in rat was reduced from 360 mg/kg/day during Week 21). There was no evidence in either species of an increase in tumors related to sumatriptan administration.

Mutagenesis

Sumatriptan was negative in in vitro (bacterial reverse mutation [Ames], gene cell mutation in Chinese hamster V79/HGPRT, chromosomal aberration in human lymphocytes) and in vivo (rat micronucleus) assays.

Impairment of Fertility

When sumatriptan was administered by subcutaneous injection to male and female rats prior to and throughout the mating period, there was no evidence of impaired fertility at doses up to 60 mg/kg/day. When sumatriptan (5, 50, 500 mg/kg/day) was administered orally to male and female rats prior to and throughout the mating period, there was a treatment-related decrease in fertility secondary to a decrease in mating in animals treated with doses greater than 5 mg/kg/day. It is not clear whether this finding was due to an effect on males or females or both.

13.2 Animal Toxicology and/or Pharmacology

Corneal Opacities: Dogs receiving oral sumatriptan developed corneal opacities and defects in the corneal epithelium. Corneal opacities were seen at the lowest dose tested, 2 mg/kg/day, and were present after 1 month of treatment. Defects in the corneal epithelium were noted in a 60-week study. Earlier examinations for these toxicities were not conducted and no-effect doses were not established.

14 CLINICAL STUDIES

In controlled clinical trials enrolling more than 1,000 patients during migraine attacks who were experiencing moderate or severe pain and 1 or more of the symptoms enumerated in [Table 3](#), onset of relief began as early as 10 minutes following a 6-mg sumatriptan injection. Lower doses of sumatriptan injection may also prove effective, although the proportion of patients obtaining adequate relief was decreased and the latency to that relief is greater with lower doses.

In Study 1, 6 different doses of sumatriptan injection (n = 30 each group) were compared with placebo (n = 62), in a single-attack, parallel-group design, the dose response relationship was found to be as shown in [Table 2](#).

Table 2: Proportion of Patients with Migraine Relief and Incidence of Adverse Reactions by Time and by Sumatriptan Dose in Study 1

Dose of Sumatriptan Injection	Percent Patients With Relief ^a				Adverse Reactions Incidence (%)
	at 10 Minutes	at 30 Minutes	at 1 Hour	at 2 Hours	
Placebo	5	15	24	21	55
1 mg	10	40	43	40	63
2mg	7	23	57	43	63
3 mg	17	47	57	60	77
4 mg	13	37	50	57	80
6 mg	10	63	73	70	83
8 mg	23	57	80	83	93

^a Relief is defined as the reduction of moderate or severe pain to no or mild pain after dosing without use of rescue medication

In 2 randomized, placebo-controlled clinical trials of sumatriptan injection 6 mg in 1,104 patients with moderate or severe migraine pain (Studies 2 and 3), the onset of relief was less than 10 minutes. Headache relief, as defined by a reduction in pain from severe or moderately severe to mild or no headache, was achieved in 70% of the patients within 1 hour of a single 6-mg subcutaneous dose of sumatriptan injection. Approximately 82% and 65% of patients treated with sumatriptan 6 mg had headache relief and were pain free within 2 hours, respectively.

Table 3 shows the 1- and 2-hour efficacy results for sumatriptan injection 6 mg in Studies 2 and 3.

Table 3: Proportion of Patients with Pain Relief and Relief of Migraine Symptoms After 1 and 2 Hours of Treatment in Studies 2 and 3

1-Hour Data	Study 2		Study 3	
	Placebo (n = 190)	Sumatriptan 6 mg (n = 384)	Placebo (n = 180)	Sumatriptan 6 mg (n = 350)
Subjects with pain relief (grade 0/1)	18%	70% ^a	26%	70% ^a
Subjects with no pain	5%	48% ^a	13%	49% ^a
Subjects without nausea	48%	73% ^a	50%	73% ^a
Subjects without photophobia	23%	56% ^a	25%	58% ^a
Subjects with little or no clinical disability ^b	34%	76% ^a	34%	76% ^a

2-Hour Data	Study 2		Study 3	
	Placebo ^c	Sumatriptan 6 mg ^d	Placebo ^c	Sumatriptan 6 mg ^d
Subjects with pain relief (grade 0/1)	31%	81% ^a	39%	82% ^a
Subjects with no pain	11%	63% ^a	19%	65% ^a
Subjects without nausea	56%	82% ^a	63%	81% ^a
Subjects without photophobia	31%	72% ^a	35%	71% ^a
Subjects with little or no clinical disability ^b	42%	85% ^a	49%	84% ^a

^a $P < 0.05$ versus placebo.

^b A successful outcome in terms of clinical disability was defined prospectively as ability to work mildly impaired or ability to work and function normally.

^c Includes patients that may have received an additional placebo injection 1 hour after the initial injection.

^d Includes patients that may have received an additional 6 mg of sumatriptan injection 1 hour after the initial injection.

Sumatriptan injection also relieved photophobia, phonophobia (sound sensitivity), nausea, and vomiting associated with migraine attacks.

The efficacy of sumatriptan injections was unaffected by whether or not the migraine was associated with aura, duration of attack, gender or age of the subject, or concomitant use of common migraine prophylactic drugs (e.g., beta-blockers).

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

- ZEMBRACE SymTouch 3 mg/0.5 mL Injection contains sumatriptan as the succinate salt and is supplied as a clear, colorless to pale yellow, sterile, nonpyrogenic solution in a prefilled, ready-to-use, single dose, disposable auto-injector unit (NDC # 67857-809-37).
- Each carton contains 4 units (NDC # 67857-809-38) and a Patient Information and Instructions for Use leaflet.

16.2 Storage and Handling

Store between 20°C and 25°C (68°F and 77°F) Excursions permitted between 15°C and 30°C (59°F and 86°F).

Protect from light.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling ([Patient Information](#) and [Instructions for Use](#)).

Risk of Myocardial Ischemia and/or Infarction, Prinzmetal's Angina, Other Vasospasm-Related Events, Arrhythmias, and Cerebrovascular Events

Inform patients that ZEMBRACE SymTouch injection may cause serious cardiovascular side effects such as myocardial infarction or stroke. Although serious cardiovascular events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, irregular heartbeat, significant rise in blood pressure, weakness, and slurring of speech and should ask for medical advice when observing any indicative sign or symptoms are observed. Apprise patients of the importance of this follow-up [*see Warnings and Precautions (5.1, 5.2, 5.4, 5.5, 5.8)*].

Anaphylactic Reactions

Inform patients that anaphylactic reactions have occurred in patients receiving sumatriptan injection. Such reactions can be life threatening or fatal. In general, anaphylactic reactions to drugs are more likely to occur in individuals with a history of sensitivity to multiple allergens [*see Contraindications (4) and Warnings and Precautions (5.9)*].

Concomitant Use with Other Triptans or Ergot Medications

Inform patients that use of ZEMBRACE SymTouch injection within 24 hours of another triptan or an ergot-type medication (including dihydroergotamine or methylsergide) is contraindicated [*see Contraindications (4), Drug Interactions (7.1, 7.3)*].

Serotonin Syndrome

Caution patients about the risk of serotonin syndrome with the use of ZEMBRACE SymTouch injection or other triptans, particularly during combined use with SSRIs, SNRIs, TCAs, and MAO inhibitors [*see Warnings and Precautions (5.7), Drug Interactions (7.4)*].

Medication Overuse Headache

Inform patients that use of acute migraine drugs for 10 or more days per month may lead to an exacerbation of headache and encourage patients to record headache frequency and drug use (e.g., by keeping a headache diary) [*see Warnings and Precautions (5.6)*].

Pregnancy

Inform patients that ZEMBRACE SymTouch injection should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus [*see Use in Specific Populations (8.1)*].

Nursing Mothers

Advise patients to notify their healthcare provider if they are breastfeeding or plan to breastfeed [*see Use in Specific Populations (8.3)*].

Ability to Perform Complex Tasks

Treatment with ZEMBRACE SymTouch injection may cause somnolence and dizziness; instruct patients to evaluate their ability to perform complex tasks during migraine attacks and after administration of ZEMBRACE SymTouch injection.

How to Use ZEMBRACE SymTouch

Provide patients instruction on the proper use of ZEMBRACE SymTouch injection if they are able to self-administer ZEMBRACE SymTouch injection in medically unsupervised conditions.

Inform patients that the needle in the ZEMBRACE SymTouch penetrates approximately $\frac{1}{4}$ of an inch (6 mm). Inform patients that the injection is intended to be given subcutaneously and intramuscular or intravascular delivery should be avoided. Instruct patients to use injection sites with an adequate skin and subcutaneous thickness to accommodate the length of the needle.

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Patient Information

ZEMBRACE SymTouch (Zem-brace Sim-Touch)

(sumatriptan succinate)

Injection

What is the most important information I should know about ZEMBRACE SymTouch?

ZEMBRACE SymTouch can cause serious side effects, including:

Heart attack and other heart problems. Heart problems may lead to death.

Stop taking ZEMBRACE SymTouch and get emergency medical help right away if you have any of the following symptoms of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

ZEMBRACE SymTouch is not for people with risk factors for heart disease unless a heart exam is done and shows no problem. You have a higher risk for heart disease if you:

- have high blood pressure
- have high cholesterol levels
- smoke
- are overweight
- have diabetes
- have a family history of heart disease

What is ZEMBRACE SymTouch?

ZEMBRACE SymTouch is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

ZEMBRACE SymTouch is not used to treat other types of headaches such as hemiplegic (that make you unable to move on one side of your body) or basilar (rare form of migraine with aura) migraines.

ZEMBRACE SymTouch is not used to prevent or decrease the number of migraine you have. It is not known if ZEMBRACE SymTouch is safe and effective in children under 18 years of age.

Who should not take ZEMBRACE SymTouch?

Do not take ZEMBRACE SymTouch if you have:

- heart problems or a history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- hemiplegic migraines or basilar migraines. If you are not sure if you have these types of migraines, ask your healthcare provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with your blood circulation
- severe liver problems
- an allergy to sumatriptan or any of the ingredients in ZEMBRACE SymTouch. See the end of this leaflet for a complete list of ingredients in ZEMBRACE SymTouch.
- taken any of the following medicines in the last 24 hours:
 - sumatriptan (IMITREX , SUMAVEL DOSE PRO, ALSUMA)
 - almotriptan (AXERT)
 - eletriptan (RELPAX)
 - frovatriptan (FROVA)
 - naratriptan (AMERGE)
 - rizatriptan (MAXALT, MAXALT-MLT)
 - sumatriptan and naproxen (TREXIMET)
 - ergotamines (CAFERGOT, ERGOMAR, MIGERGOT)
 - dihydroergotamine (D.H.E. 45, MIGRANAL)

Ask your healthcare provider if you are not sure if your medicine is listed above.

What should I tell my healthcare provider before taking ZEMBRACE SymTouch?

Before you take ZEMBRACE SymTouch, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure
- have high cholesterol

- have diabetes
- smoke
- are overweight
- have heart problems or family history of heart problems or stroke
- have kidney problems
- have liver problems
- have had epilepsy or seizures
- are not using effective birth control
- become pregnant while taking ZEMBRACE SymTouch
- are breastfeeding or plan to breastfeed. ZEMBRACE SymTouch passes into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take ZEMBRACE SymTouch.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using ZEMBRACE SymTouch with certain other medicines can affect each other, causing serious side effects.

Especially tell your healthcare provider if you take anti-depressant medicines called:

- selective serotonin reuptake inhibitors (SSRIs)
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- tricyclic antidepressants (TCAs)
- monoamine oxidase inhibitors (MAOIs)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take ZEMBRACE SymTouch?

- Certain people should take their first dose of ZEMBRACE SymTouch in their healthcare provider's office or in another medical setting. Ask your healthcare provider if you should take your first dose in a medical setting.
- Use ZEMBRACE SymTouch exactly as your healthcare provider tells you to use it.
- Your healthcare provider may change your dose. Do not change your dose without first talking with your healthcare provider.

- For adults, the usual dose is a single injection given just below the skin.
- You should give an injection as soon as the symptoms of your headache start, but it may be given at any time during a migraine headache attack.
- If you did not get any relief after the first injection, do not give a second injection without first talking with your healthcare provider.
- If your headache comes back or you only get some relief after your first injection, you can take a second injection 1 hour after the first injection, but not sooner.
- Do not take more than a total of 12 mg in a 24-hour period. For example, you may give one 3mg injection four times a day, at least 1 hour apart.
- If you use too much ZEMBRACE SymTouch, call your healthcare provider or go to the nearest hospital emergency room right away.
- You should write down when you have headaches and when you take ZEMBRACE SymTouch so you can talk with your healthcare provider about how ZEMBRACE SymTouch is working for you.

What should I avoid while taking ZEMBRACE SymTouch?

ZEMBRACE SymTouch can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything where you need to be alert.

What are the possible side effects of ZEMBRACE SymTouch?

See [“What is the most important information I should know about Zembrace SymTouch?”](#)

ZEMBRACE SymTouch may cause serious side effects, including:

- **changes in color or sensation in your fingers and toes (Raynaud’s syndrome)**
- **stomach and intestinal problems** (gastrointestinal and colonic ischemic events). Symptoms of gastrointestinal and colonic ischemic events include:
 - sudden or severe stomach pain
 - stomach pain after meals
 - weight loss
 - nausea or vomiting
 - constipation or diarrhea
 - bloody diarrhea
 - fever
- **problems with blood circulation to your legs and feet (peripheral vascular ischemia).** Symptoms of peripheral vascular ischemia include:
 - cramping and pain in your legs or hips

- feeling of heaviness or tightness in your leg muscles
- burning or aching pain in your feet or toes while resting
- numbness, tingling, or weakness in your legs
- cold feeling or color changes in 1 or both legs or feet
- **hives (itchy bumps); swelling of your tongue, mouth, or throat.**
- **medication overuse headaches.** Some people who use too many ZEMBRACE SymTouch injections may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with ZEMBRACE SymTouch.
- **serotonin syndrome.** Serotonin syndrome is a rare but serious problem that can happen in people using ZEMBRACE SymTouch, especially if ZEMBRACE SymTouch is used with anti-depressant medicines called SSRIs or SNRIs.

Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:

- mental changes such as seeing things that are not there (hallucinations), agitation, or coma
- fast heartbeat
- changes in blood pressure
- high body temperature
- tight muscles
- trouble walking
- **seizures.** Seizures have happened in people taking ZEMBRACE SymTouch who have never had seizures before. Talk with your healthcare provider about your chance of having seizures while you take ZEMBRACE SymTouch.

The most common side effects of ZEMBRACE SymTouch include:

- pain or redness at your injection site
- tingling or numbness in your fingers or toes
- dizziness
- warm, hot, burning feeling to your face (flushing)
- discomfort or stiffness in your neck
- feeling weak, drowsy, or tired

Tell your healthcare provider if you have any side effect that bothers you or that does not go

away.

These are not all the possible side effects of ZEMBRACE SymTouch. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1- 800-FDA-1088.

How should I store ZEMBRACE SymTouch?

- Store between 68° and 77°F (20° and 25°C)
- Store your medicine away from light.
- Keep your medicine in the packaging or carrying case provided with it.

Keep ZEMBRACE SymTouch and all medicines out of the reach of children.

General information about the safe and effective use of ZEMBRACE SymTouch.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use ZEMBRACE SymTouch for a condition for which it was not prescribed. Do not give ZEMBRACE SymTouch to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about ZEMBRACE SymTouch. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ZEMBRACE SymTouch that is written for healthcare professionals.

For more information, go to www.drreddys.com or call 1-888-966-8766.

What are the ingredients in ZEMBRACE SymTouch Injection?

Active ingredient: sumatriptan succinate

Inactive ingredients: sodium chloride, water for injection

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