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Plan for Supporting Safe Collection and Proper Disposal of Home Generated Sharps

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GSK Self-Injectable Products Subject To These Regulations

GSK currently markets, distributes, and/or sells two self-injectable products. The brand names of these products are Imitrex® (sumatriptan succinate) Injection and ARIXTRA® (fondaparinux sodium) Injection.

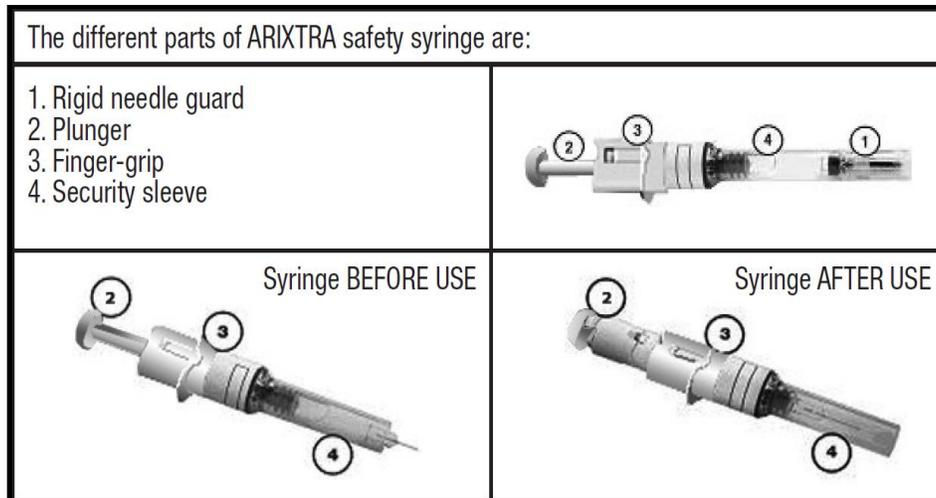
ARIXTRA® is indicated for the prevention of blood clots after hip fracture, hip or knee replacement surgery or in certain patients after abdominal surgery. This medication is also indicated for the treatment of blood clots. The usual duration of administration of ARIXTRA® is five to nine days.

Imitrex® is indicated for the acute treatment of migraine attacks. There are 2 basic types of migraine-specific therapies — acute and preventative. Acute medications are designed to relieve a migraine after it starts, and preventative medications are designed to help eliminate or significantly reduce the frequency of a person's migraines. Imitrex® Injection is indicated for 1) the acute treatment of migraine attacks with or without aura in adults and 2) the acute treatment of cluster headache episodes in adults. Patients are instructed to administer via injection this medication in accordance with the instruction of a physician or other suitably qualified health care professional.

GSK Supports Safe Collection and Proper Disposal of Home Generated Sharps

GSK has demonstrated a strong commitment to the safe and proper use and disposal of its self-injectable medications. Patient safety and needle stick injury prevention were given serious consideration as the above-mentioned products were being developed. In fact, inherent in the design of both products, GSK used safe needle technology to shield the sharps and provides, at a minimum, approved sharps containers for home generated sharps waste materials.

Specifically, ARIXTRA® uses a 27 gauge needle that is only a half-inch long and the automatic needle protection system retracts the needle once medication is dispensed. As part of the prescribing information, Patient Instructions for self-administration are provided to guide patients on how to appropriately inject the product. Additionally, within the Patient Information Leaflet, patients are guided to follow the instructions given their nurse or doctor about the right way to dispose of used syringes and needles. The leaflet also notes that there may be state laws about the right way to dispose of used syringes, needles, and disposal



Additionally, patients or Healthcare professionals may call the GSK Customer Care Call Center to receive disposal instructions (including California specific requirements), through a number provided in the prescribing information.

Imitrex® Injection is available in the easy-to-use Imitrex® STATdose System, which allows patients to conveniently administer Imitrex with just the push of a button.

The Imitrex® STATdose System includes two small, disposable cartridges pre-filled with a single dose of Imitrex®, and an easy to use autoinjector pen that allows patients to self-administer the medication about one-quarter inch under the skin. With the Imitrex® STATdose System, patients can treat migraines quickly and conveniently while avoiding direct contact with a needle or syringe. After injection, the used sharp is placed into the empty cartridge. The California Department of Health, Medical Waste Management Office has designated the empty cartridge as an approved sharps container that is suitable for transportation to an approved collection facility. Disposal instructions (including California specific requirements), are provided through an 800 number which connects to the GSK Customer Care Call Center.



General Instructions To Patients On The Safe Storage and Disposal of Home Generated Sharps(The GSK call center provides additional instructions for consumers located in California)

Collection and Storage

- Place used needles, syringes, lancets and other sharps devices in a container approved for the storage of sharps.
- When your sharps disposal container is about three-quarters (3/4) full, follow your community guidelines for proper disposal methods. Do not throw sharps in the trash in the State of California.
- Keep sharps storage containers away from children and pets
- Do not place loose needles or other sharps in the household or public trash cans or recycling
- Do not flush loose needles and other sharps down the toilet
- Do not attempt to remove the needle without a proper needle destruction device

Sharps Disposal Options

Current best practices have been recommended by the EPA¹, FDA², and state and local municipalities throughout the United States. Current disposal options generally accepted for home generated sharps waste include the following:

- **Drop-Off Collection Sites** - Where available, home generators take filled sharps containers or other appropriate rigid storage container, to appropriate collection sites. These may include doctors' offices, hospitals, health clinics, pharmacies, police and fire stations, and medical waste facilities.
- **Household Hazardous Waste Collection Sites** – Where available, home generators take filled sharps containers or other appropriate rigid storage container to municipal household hazardous waste/recyclable waste collection sites for proper disposal.
- **Needle Exchange Programs** – Used sharps are exchanged for clean unused devices and the used sharps are properly managed and disposed of by the clinic or exchange venue. These programs are intended for illicit drug users and are not typically used by a prescription patient to obtain an injection device. However, the exchange venue can serve as a disposal location for a prescription patient.

In summary, GlaxoSmithKline supports the safe collection and proper disposal of home generated sharps by providing at no cost to the patient, educational materials on proper sharps disposal. Patients may contact our Toll Free Customer Call Center Hotline to obtain California specific disposal information including the locations of sharps collection facilities near their homes where they can dispose of their sharps free of charge.

¹ EPA Website <http://www.epa.gov/wastes/nonhaz/industrial/medical/disposal.htm>

2. FDA Website:

[http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=sharps disposal&utm_content=1](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=sharps%20disposal&utm_content=1)