

## **Safe Needle Collection and Disposal Plan**

### Patient Education Regarding Collection of Sharps Waste

UCB, Inc. is committed to ensuring the proper collection and treatment of CIMZIA prefilled syringes for patients who self-inject at home by educating consumers about proper collection and treatment methods on CIMZIA.com and via:

- CIMZIA Prescribing Information
- CIMZIA Medication Guide
- CIMZIA prefilled syringe self-administration video

### Description of Sharps Disposal by Mail System®

When healthcare professionals prescribe CIMZIA, they provide patients with educational materials in a patient information kit. The kit includes information about the end-of-life product management called CIMZIA Sharps Disposal by Mail System and a postage-paid business reply card enrollment form for patients to sign up for the program. CIMZIA patients will receive their free mail-back system shipped directly to their home within several days of enrollment to begin proper containment and disposal of their used CIMZIA syringes/needles. Additional Sharps Disposal by Mail System program support is available by calling CIMZIA patient support at 1-866-424-4942 or via CIMZIA.com.

The CIMZIA Sharps Disposal by Mail System is available nationwide at no cost to the patient. Patients will continue to receive this free mail-back system as long as they remain on CIMZIA therapy and continue to return the system with the used injection devices approximately every 6 months.

The mail-back system includes: an FDA-approved 1-gallon, puncture-resistant, white sharps collection container with a tethered leak-proof lid closure, which includes a unique opening designed specifically for CIMZIA syringes; Sharps Disposal by Mail System instructions for use and a welcome letter; a postage-paid shipping box with a liner, plastic bag, twist tie, secure closure tape, and outer branding sleeve; a manifest tracking form; and a CIMZIA package insert, which includes full Prescribing Information and Medication Guide.

See below for a pictorial of the system and its components:



By following the Sharps Disposal by Mail System instructions, patients' used CIMZIA pre-filled syringes will be properly treated and repurposed by Sharps Compliance, Inc. Upon filling the collection device, patients may either hand the box to their U.S. mail carrier or drop it off at the U.S. Postal Service (USPS) or anywhere the USPS arranges pickup. The Sharps Disposal by Mail System is in compliance with USPS regulations.

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This comprehensive mail-back system eliminates the need for patients taking CIMZIA to check with their doctor or pharmacist about lawful ways to dispose of used needles and prefilled syringes/injection devices. State-specific guidance for disposal methods is difficult to find, so the approved mail-back system addresses patients' needs with one solution.

CIMZIA patients are advised of the following general sharps waste handling guidelines:

- Do not attempt to recap the needle.
- Check with your doctor for instructions on the right way to throw away your used needles and used prefilled syringes. There may be special state or local laws about throwing away used needles and syringes.
- Ask your doctor or pharmacist about how to get a puncture-proof container ("sharps" container) that will meet the requirements of your particular state or town. When the container is two-thirds full, tape the lid closed.
- Dispose of the container as instructed by your doctor, nurse or pharmacist. Do not throw away the container in the trash or recycle.
- Always keep CIMZIA, injection supplies, puncture-proof container, and all other medicines out of the reach of children.

### Patient Involvement

The CIMZIA Sharps Disposal by Mail System was developed using market research and feedback from patients and healthcare professionals. Returns of the system are tracked weekly and reviewed monthly. UCB reaches out to patients, medical waste treatment partners, and the USPS periodically through surveys to gauge satisfaction and explore opportunities for improvement in the mail-back program.

### Environmental/Product Stewardship

By using the CIMZIA Sharps Disposal by Mail System, patients will be helping to protect the environment. Our program partner, Sharps Compliance, converts all of the returned material from CIMZIA patients into a raw material used in industrial applications The Waste Conversion Process™ (WCP) produces a product called PELLA-DRX™ (see picture below).



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PELLA-DRX is the end product of the WCP, a stringent method that renders the origin of the product indistinguishable while removing associated hazards from the medical waste.

**This process greatly reduces landfill use for all CIMZIA Sharps Disposal by Mail System returns.**

#### California Household Sharps Waste Handling Guidelines

CIMZIA patients who reside in California and self-inject at home are required by law to safely dispose of their used CIMZIA prefilled syringes. To learn more about disposal options, patients can talk to their doctor or pharmacist or visit

<http://www.calrecycle.ca.gov/HomeHazWaste/Sharps>, which lists approved drop-off/collection facilities.

UCB, Inc. has submitted this sharps-waste collection plan to the California Department of Resources, Recycling and Recovery per California Senate Bill 486. The bill requires pharmaceutical manufacturers that sell or distribute medication that can be self-injected at home to submit a plan for safe collection and disposal of used syringes. UCB's plan description and other pharmaceutical companies plan descriptions are available on the CalRecycle Web site:

<http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Reporting/default.htm/Reporting/default.htm>

#### National Programs for Medical Waste Disposal

The Sharps Disposal by Mail System is free to CIMZIA patients on a nationwide basis. However, patients in states outside of California can consult their specific states' Web sites to learn how to properly dispose of needles, syringes, and other sharps or visit:

United States Environmental Protection Agency:

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

The Coalition for Safe Community Needle Disposal:

<http://www.safeneedledisposal.org>

#### Coordination

UCB, Inc. supports efforts by retailers, pharmaceutical distributors, manufacturers of injection devices, and other partners, including local governments, healthcare organizations, public health officers, solid waste service providers, and other groups with interest in protecting public health and safety through the safe collection and proper disposal of waste devices, including sharps.

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## UCB, Inc. Contact Information

If you would like assistance from UCB, Inc. in identifying your disposal options, please contact a CIMZIA representative at 1-866-4-CIMZIA. Representatives are available to assist patients with questions about rheumatoid arthritis and Crohn's disease treatment, including product administration and medical waste disposal.

UCB, Inc. will post and maintain a copy of its Safe Needle Collection and Disposal Plan on its Web site ([www.cimzia.com](http://www.cimzia.com)).

### **Important Safety Information you should know about CIMZIA® (certolizumab pegol).**

#### **What is the most important information I should know about CIMZIA?**

CIMZIA is a medicine that affects your immune system. CIMZIA can lower the ability of the immune system to fight infections. **Serious infections have happened in patients taking CIMZIA, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients have died from these infections.**

- Your doctor should test you for TB before starting CIMZIA.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with CIMZIA.

#### **Certain Types of Cancer**

There have been cases of unusual cancers in children and teenage patients using TNF-blocking agents. CIMZIA is not approved for use in pediatric patients. For people taking TNF-blocker medicines, including CIMZIA, the chances for getting lymphoma or other cancers may increase. People with RA, especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma.

#### **What is CIMZIA?**

CIMZIA is a medicine called a Tumor Necrosis Factor (TNF) blocker. CIMZIA is used in adult patients to:

- Lessen the signs and symptoms of moderately to severely active Crohn's disease (CD) in adults who have not been helped enough by usual treatments.
- Treat moderately to severely active rheumatoid arthritis (RA).

#### **Before starting CIMZIA, tell your doctor about all of your medical conditions, including if you:**

- Think you have an infection. You should not start taking CIMZIA if you have any kind of infection.
- Are being treated for an infection
- Have signs of an infection, such as a fever, cough, flu-like symptoms
- Have any open cuts or sores on your body
- Get a lot of infections or have infections that keep coming back
- Have diabetes
- Have HIV
- Have TB, or have been in close contact with someone with TB
- Were born in, lived in, or traveled to countries where there is more risk of getting TB. Ask your doctor if you are not sure.
- Live or lived in certain parts of country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may develop or become severe if you take CIMZIA. If you do not know if you have lived in these types of areas, ask your doctor.
- Have or have had hepatitis B
- Have or have had any type of cancer

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- Have congestive heart failure
- Have seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis
- Are scheduled to receive a vaccine. Do not receive a live vaccine while taking CIMZIA
- Are pregnant, planning to become pregnant, or breastfeeding. CIMZIA has not been studied in pregnant or nursing women.
- Are allergic to any of the ingredients in CIMZIA.
- Are taking any medicines, including prescription and nonprescription medicines, vitamins and herbal supplements. Your doctor will tell you if it is okay to take your other medicines while taking CIMZIA.
- Especially tell your doctor if you take:  
Kineret® (anakinra), Orencia® (abatacept), Rituxan® (rituximab), Tysabri® (natalizumab). You have a higher chance for serious infections when taking CIMZIA with these medicines.  
A TNF blocker: Remicade® (infliximab), Humira® (adalimumab), Enbrel® (etanercept) or Simponi® (golimumab)

You should not take CIMZIA while you take one of these medicines.

### **How should I use CIMZIA?**

CIMZIA is available as a lyophilized powder for reconstitution or a prefilled syringe. If your doctor prescribes the lyophilized pack, CIMZIA should be injected by a healthcare provider. If your doctor prescribes the prefilled syringe, see the section "Patient Instructions for Use" at the end of the Medication Guide for complete instructions for use. Do not give yourself an injection of CIMZIA unless you have been shown by your doctor or nurse, or they can train someone you know to help you with your injection. CIMZIA is given by an injection under the skin. Your doctor will tell you how much CIMZIA to inject and how often, based on your condition to be treated. Make sure to keep all of your injection and follow-up appointments with your doctor.

**After starting CIMZIA**, if you get an infection, any sign of an infection including a fever, cough, flu-like symptoms, or have open cuts or sores on your body, call your doctor right away. CIMZIA can make you more likely to get infections or make any infection that you may have worse.

### **What are the possible side effects of CIMZIA?**

#### **CIMZIA can cause serious side effects including:**

- **Heart Failure** including new heart failure or worsening of heart failure you already have. Symptoms include shortness of breath, or swelling of your ankles or feet.
- **Nervous System Problems** such as Multiple Sclerosis, seizures, or inflammation of the nerves of the eyes. Symptoms include dizziness, numbness or tingling, problems with your vision, and weakness in your arms or legs.
- **Allergic Reactions.** Signs of an allergic reaction include a skin rash, swollen face, or trouble breathing.
- **Hepatitis B virus reactivation in patients who carry the virus in their blood.** In some cases, patients have died as a result of hepatitis B virus being reactivated. Your doctor should monitor you carefully during treatment with CIMZIA if you carry the hepatitis B virus in your blood. Tell your doctor if you have any of the following symptoms: feel unwell, poor appetite, tiredness (fatigue), fever, skin rash, or joint pain.
- **Blood Problems.** Your body may not make enough of the blood cells that help fight infections or help stop bleeding. Symptoms include a fever that doesn't go away, bruising or bleeding very easily, or looking very pale.
- **Immune reactions including a lupus-like syndrome.** Symptoms include shortness of breath, joint pain, or a rash on the cheeks or arms that worsens with sun exposure.

**Call your doctor right away if you develop any of the above side effects or symptoms.**

**The most common side effects of CIMZIA are:** upper respiratory infections (flu, cold), rash, and urinary tract infections (bladder infections).

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Other side effects have happened in some people including new psoriasis or worsening of psoriasis you already have and injection site reactions. Tell your doctor about any side effect that bothers you or does not go away. These are not all of the side effects with CIMZIA. Ask your doctor or pharmacist for more information.

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

**Please see the Medication Guide for CIMZIA and discuss it with your doctor.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**