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® (certolizumab pegol) prefilled syringes for patients who self-inject at home by educating consumers about proper collection and disposal of used CIMZIA prefilled syringes on CIMZIA.com and via:

- CIMZIA Prescribing Information
- CIMZIA Prefilled Syringe Patient Instructions for Use Booklet
- CIMZIA prefilled syringe self-administration video

Description of Sharps Recovery System™

When healthcare professionals prescribe CIMZIA, they can provide patients with educational materials in a patient information kit. The kit includes information about the end-of-life product management called Sharps Recovery 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 Recovery System program support is available by calling CIMZIA patient support at 1-866-424-6942 or via CIMZIA.com.

The Sharps Recovery 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 Recovery 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 Recovery System instructions, patients' used CIMZIA prefilled 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 Recovery System is in compliance with USPS regulations.

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 Sharps Recovery 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 Sharps Recovery 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).

Introducing PELLA-DRX™

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 Sharps Recovery 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 Recovery 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.

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, psoriatic arthritis, ankylosing spondylitis, and Crohn's disease, 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 (http://ucb-usa.com/about-ucb/Products).

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

You should not start receiving CIMZIA if you have any kind of infection unless your healthcare provider says it is okay.

Before you receive CIMZIA, tell your healthcare provider if you:
- think you have an infection, flu-like symptoms, or have any other symptoms of an infection such as:
  - fever, sweat, or chills
  - muscle aches
  - cough
  - diarrhea or stomach pain
  - burning when you urinate or urinate more often than normal
  - weight loss
  - warm, red, or painful skin or sores on your body
  - shortness of breath
  - blood in phlegm
  - feeling very tired
- are being treated for an infection, or get a lot of infections or have infections that keep coming back
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have tuberculosis (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 healthcare provider if you are not sure.
- live or have lived in certain parts of the 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 more severe if you take CIMZIA. If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, or blastomycosis is common, ask your healthcare provider.
- have or have had hepatitis B
- use the medicine Kineret® (anakinra), Orencia® (abatacept), Rituxan® (rituximab), or Tysabri® (natalizumab)

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 healthcare provider right away. CIMZIA can make you more likely to get infections or make any infection that you may have worse.

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 prescription 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 patients who have not been helped enough by usual treatments.
- Treat moderately to severely active rheumatoid arthritis (RA).
- Treat active psoriatic arthritis (PsA).
- Treat active ankylosing spondylitis (AS)

What should I tell my healthcare provider before starting treatment with CIMZIA?
CIMZIA may not be right for you. Before starting CIMZIA, tell your healthcare provider about all of your medical conditions, including if you:
- have an infection
- have or have had any type of cancer
- 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 allergic to any of the ingredients in CIMZIA
- are pregnant or planning to become pregnant. It is not known if CIMZIA will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving CIMZIA.

  Pregnancy Registry: If you become pregnant while taking CIMZIA, talk to your healthcare provider about registering in the pregnancy exposure registry for CIMZIA. You can enroll in this registry by calling 1-877-311-8972. The purpose of this registry is to collect information about the safety of CIMZIA during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if CIMZIA passes into your breast milk. You and your healthcare provider should decide if you will receive CIMZIA or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take the following medicines due to a higher chance for serious infections:
- Kineret® (anakinra), Orencia® (abatacept), Rituxan® (rituximab), or Tysabri® (natalizumab)
- medicines called Tumor Necrosis Factor (TNF) blockers, such as Remicade® (infliximab), Humira® (adalimumab), Enbrel® (etanercept), or Simponi® (golimumab)

Ask your healthcare provider if you are not sure. You should not take CIMZIA while you take any of these medicines.

How should I receive CIMZIA?
CIMZIA comes as a lyophilized powder or a solution in a prefilled syringe for injection. If your healthcare provider prescribes the CIMZIA powder, CIMZIA should be injected by a healthcare provider. If your healthcare provider prescribes the prefilled syringe, you will be trained on how to inject CIMZIA. See the booklet called "Instructions for Use" packaged in your CIMZIA prefilled syringe kit for complete instructions for use. Do not give yourself an injection of CIMZIA unless you have been shown by your healthcare provider, or they can train someone you know to help you with your injection. CIMZIA is given by an injection under the skin. Your healthcare provider will tell you how much and how often to inject CIMZIA. Do not use more CIMZIA or inject more often than prescribed.

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, swelling of your ankles or feet, or sudden weight gain.
- **Allergic Reactions.** Signs of an allergic reaction include a skin rash, swelling or itching of the face, tongue, lips, or throat, 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 healthcare provider should monitor you carefully before and during treatment with CIMZIA to see if you carry the hepatitis B virus in your blood. Tell your healthcare provider if you have any of the following symptoms:
  - feel unwell
  - skin or eyes look yellow
  - tiredness (fatigue)
  - poor appetite or vomiting
  - pain on the right side of your stomach (abdomen)
- **New or worsening nervous system problems,** such as multiple sclerosis (MS), Guillain-Barre syndrome, seizures, or inflammation of the nerves of the eyes. Symptoms may include:
  - dizziness
  - numbness or tingling
  - problems with your vision
  - weakness in your arms or legs
- **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 healthcare provider right away if you have any side effects listed above.
The most common side effects of CIMZIA include: upper respiratory infections (flu, cold), rash, and urinary tract infections (bladder infections).
Tell your healthcare provider about any side effect that bothers you or does not go away. These are not all of the possible side effects of CIMZIA. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the Medication Guide for CIMZIA and discuss it with your healthcare provider.

CIMZIA®
(certolizumab pegol)

Medication Guide

CIMZIA® (CIM-zee-uh)

(certolizumab pegol)

lyophilized powder or solution for subcutaneous use

Read the Medication Guide that comes with CIMZIA before you start using it, and before each injection of CIMZIA. This Medication Guide 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 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. These infections include tuberculosis (TB) and infections caused by viruses, fungi or bacteria that have spread throughout the body. Some patients have died from these infections.

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

You should not start receiving CIMZIA if you have any kind of infection unless your healthcare provider says it is okay.

Before you receive CIMZIA, tell your healthcare provider if you:

° Think you have an infection, flu-like symptoms, or have any other symptoms of an infection such as:

- fever, sweat, or chills
- muscle aches
- cough
- shortness of breath
- blood in phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more often than normal
- feeling very tired

- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.

- have tuberculosis (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 for getting TB. Ask your healthcare provider if you are not sure.
- live or have lived in certain parts of the 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 more severe if you take CIMZIA. If you do not know if you have lived in an area where histoplasmosis, coccidioidomycosis, or blastomycosis is common, ask your healthcare provider.
- have or have had hepatitis B
- use the medicine Kineret® (anakinra), Orencia® (abatacept), Rituxan® (rituximab), or Tysabri® (natalizumab)

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 healthcare provider right away. CIMZIA can make you more likely to get infections or make any infection that you may have worse.

Certain types of Cancer

- There have been cases of unusual cancers in children and teenage patients using TNF-blocking agents.
- For people taking TNF-blocker medicines, including CIMZIA, the chances of 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.

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- Treat moderately to severely active rheumatoid arthritis (RA)
- Treat active psoriatic arthritis
- Treat active ankylosing spondylitis

What should I tell my healthcare provider before starting treatment with CIMZIA?

CIMZIA may not be right for you. Before starting CIMZIA, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection**.** (See, "What is the most important information I should know about CIMZIA?")
- have or have had any type of cancer.
- 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 allergic to any of the ingredients in CIMZIA**.** See the end of this Medication Guide for a list of the ingredients in CIMZIA.
- are pregnant or planning to become pregnant. It is not known if CIMZIA will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while receiving CIMZIA.

  Pregnancy Registry: If you become pregnant while taking CIMZIA, talk to your healthcare provider about registering in the pregnancy exposure registry for CIMZIA. You can enroll in this registry by calling 1-877-311-8972. The purpose of this registry is to collect information about the safety of CIMZIA during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if CIMZIA passes into your breast milk. You and your healthcare provider should decide if you will receive CIMZIA or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Especially tell your healthcare provider if you take the following medicines due to a higher chance for serious infections:

- Kineret® (anakinra), Orencia® (abatacept), Rituxan® (rituximab), or Tysabri® (natalizumab).
- medicines called Tumor Necrosis Factor (TNF) blockers such as Remicade® (infliximab), Humira® (adalimumab), Enbrel® (etanercept), or Simponi® (golimumab).

Ask your healthcare provider if you are not sure.

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

How should I receive CIMZIA?

- CIMZIA comes as lyophilized powder or as a solution in a prefilled syringe for injection.
- If your healthcare provider prescribes the CIMZIA powder, your CIMZIA should be injected by a healthcare provider. Each dose of CIMZIA will be given as 1 or 2 separate injections under the skin in your stomach area or upper thighs.
- If your healthcare provider prescribes the CIMZIA prefilled syringe, you will be trained on how to inject CIMZIA.
- You will receive a **CIMZIA Prefilled Syringe Kit** including a complete **"Instructions for Use"** booklet for the right way to inject CIMZIA.
- Read the detailed Instructions for Use booklet for instructions about how to prepare and inject your dose of CIMZIA, and how to properly throw away used syringes containing the needle.
- Do not give yourself an injection of CIMZIA unless you have been shown by your healthcare provider. A family member or friend can also be trained to help you give your injection. Talk to your healthcare provider if you have questions.
- CIMZIA is given by an injection under the skin. Your healthcare provider will tell you how much and how often to inject CIMZIA. Do not use more CIMZIA or inject more often than prescribed.
- You may need more than 1 injection at a time depending on your prescribed dose of CIMZIA.
- CIMZIA may be injected into your stomach or upper thighs. If you are prescribed more than 1 injection, each injection should be given at a different site in your stomach or upper thighs.
- Make sure the solution in the prefilled syringe is clear to colorless to light yellow. The solution should be mostly free from particles. **Do not use the CIMZIA prefilled syringe if the medicine looks cloudy or if there are large or colored particles.**
- Do not miss any doses of CIMZIA. If you miss a dose, call your healthcare provider or pharmacist for instructions.
- Make sure to keep all follow-up appointments with your healthcare provider.

What are the possible side effects of CIMZIA?
CIMZIA can cause serious side effects including:

- **See** "**What is the most important information I should know about CIMZIA?**"
- **Heart Failure** including new heart failure or worsening of heart failure you already have. Symptoms include shortness of breath, swelling of your ankles or feet, or sudden weight gain.

- **Allergic Reactions.** Signs of an allergic reaction include a skin rash, swelling or itching of the face, tongue, lips, or throat, 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 before and during treatment with CIMZIA to see if you carry the hepatitis B virus in your blood. Tell your doctor if you have any of the following symptoms:
    - feel unwell
    - skin or eyes look yellow
    - tiredness (fatigue)
    - poor appetite or vomiting
    - pain on the right side of your stomach (abdomen)

- **New or worsening nervous system problems,** such as multiple sclerosis (MS), Guillain-Barre syndrome, seizures, or inflammation of the nerves of the eyes. Symptoms may include:
    - dizziness
    - numbness or tingling
    - problems with your vision
    - weakness in your arms or legs

- **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 healthcare provider right away if you have any serious side effects listed above.

The most common side effects of CIMZIA include:

- upper respiratory infections (flu, cold)
- rash
- urinary tract infections (bladder infections)

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

These are not all of the possible side effects of CIMZIA. 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 CIMZIA?

- Keep CIMZIA in the refrigerator between 36ºF to 46ºF (2ºC to 8ºC).
- Do not freeze CIMZIA.
- Protect CIMZIA from light**.** Store CIMZIA in the carton it came in.
- Do not use CIMZIA if the medicine is expired. Check the expiration date on the prefilled syringe or carton.
- The CIMZIA prefilled syringe is made of glass. Do not drop or crush the syringe.

Keep CIMZIA and all medicines out of the reach of children.

General information about the safe and effective use of CIMZIA.

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

This Medication Guide summarizes the most important information about CIMZIA. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about CIMZIA that is written for health professionals.

For more information, go to www.CIMZIA.com or call 1-866-424-6942.

What are the ingredients in CIMZIA?

CIMZIA lyophilized powder:

Active ingredient: certolizumab pegol

Inactive ingredients: lactic acid, polysorbate, sucrose

CIMZIA lyophilized powder is mixed with sterile Water for Injection.

CIMZIA prefilled syringe:

Active ingredient: certolizumab pegol

Inactive ingredients: sodium acetate, sodium chloride, Water for Injection

CIMZIA has no preservatives.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Product manufactured by:

UCB, Inc.

1950 Lake Park Drive

Smyrna, GA 30080

US License No. 1736

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