MEDICATION GUIDE
CIMZIA® (CIM-zee-uh)
(certolizumab pegol)

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 doctor 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 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.

Before starting CIMZIA, tell your doctor 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 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 doctor 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 doctor.
- 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 doctor 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.

See the section "What are the possible side effects of CIMZIA?" for more information.

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).

It is not known whether CIMZIA is safe and effective in children.

What should I tell my doctor before starting treatment with CIMZIA?

CIMZIA may not be right for you. Before starting CIMZIA, tell your doctor 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.

Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding.

Pregnancy Registry: To monitor the outcomes of pregnant women exposed to CIMZIA, a registry for pregnant women who take CIMZIA has been established. The purpose of this registry is to check the health of the pregnant mother and her child. Talk to your doctor if you are pregnant and contact the registry at 1-877-311-8972.

Tell your doctor about all the medicines you take 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 Kineret®, Orencia®, Rituxan®, or Tysabri®.
- A TNF blocker: Remicade® (infliximab), Humira® (adalimumab), Enbrel® (etanercept), Simponi™ (golimumab).

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

How should I use CIMZIA?
Lyophilized Powder for Reconstitution:

- If your doctor prescribes the CIMZIA powder for reconstitution, CIMZIA should be injected by a healthcare provider. Each dose of CIMZIA will be given as one or two separate injections under the skin in your stomach area (abdomen) or upper leg (thigh).

- Make sure to keep all of your injection and follow-up appointments with your doctor.

Prefilled Syringe:

- If your doctor prescribes the CIMZIA prefilled syringe, see the booklet called **"Patient Instructions for Use"** packed 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 doctor or nurse. Call your doctor if you have questions. Someone you know can also help you with your injection after they have been trained by your doctor or nurse.

- CIMZIA is given by an injection under the skin. Your doctor will tell you how much CIMZIA to inject and how often to inject CIMZIA, based on your condition to be treated. Do not use more CIMZIA or inject more often than prescribed.

- Depending on the amount of CIMZIA prescribed by your doctor, you may need more than one injection at a time.

- If you are prescribed to take 400 mg of CIMZIA, you will need two injections. You will need to use two CIMZIA prefilled syringes.

- CIMZIA may be injected into your abdomen or thigh area. If you are prescribed to have more than one injection, each injection should be given at a different site in your abdomen or thigh.

- Make sure the solution in the prefilled syringe is clear and colorless to light yellow. The solution should be essentially 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 forget to take CIMZIA, inject a dose as soon as you remember. Then, take your next dose at your regularly scheduled time.

- Make sure to keep all follow-up appointments with your doctor.

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.
- **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, swelling 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 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.

Reference ID: 3180234

The most common side effects in people taking CIMZIA are:

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

Other side effects with CIMZIA include:

- **Psoriasis.** Some people using CIMZIA had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus. Your doctor may decide to stop your treatment with CIMZIA.

- **Injection site reactions**. Redness, rash, swelling, itching or bruising can happen in some people. These symptoms will usually go away within a few days. If you have pain, redness, or swelling around the injection site that doesn't go away within a few days or gets worse, call your doctor right away.

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.

General information about CIMZIA

Medicines are sometimes prescribed for purposes that are not mentioned in Medication Guides. 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 condition. It may harm them.

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

For more information go to www.CIMZIA.com or you can enroll in a patient support program by calling 1-866-4CIMZIA (424-6942).

How should I store CIMZIA?

- Keep CIMZIA in the refrigerator at 36ºF – 46ºF (2ºC – 8ºC)
- Let CIMZIA come to room temperature before injecting it.
- **Do not freeze** CIMZIA.
- **Protect** CIMZIA **from light.** Store CIMZIA in the carton.

- Do not use CIMZIA if the medication is expired (today's date is past the date printed on the vial, prefilled syringe or carton), or if the liquid looks cloudy or discolored.

The vials and prefilled syringe are glass. Do not drop or crush them.

Always keep CIMZIA, injection supplies, puncture-proof container, and all other medicines out of the reach of children.

What are the ingredients in CIMZIA?
CIMZIA lyophilized powder:
Active ingredient: certolizumab pegol.
Inactive ingredients: sucrose, lactic acid, polysorbate.
The pack contains Water for Injection, for reconstitution of the lyophilized powder.

CIMZIA prefilled syringe:
Active ingredient: certolizumab pegol
Inactive ingredients: sodium acetate, sodium chloride, and Water for Injection.
CIMZIA has no preservatives.

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

Product developed and manufactured for:
UCB, Inc.
1950 Lake Park Drive
Smyrna, GA 30080

US License No. 1736

Revised 08/2012