

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

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

### CIMZIA may cause serious side effects, including:

- **CIMZIA is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker** that can lower the ability of your immune system to fight infections. Some people who received CIMZIA have developed serious infections, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some of these serious infections have caused hospitalization and death.

- 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.

### Before starting CIMZIA, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:
  - o fever, sweat, or chills
  - o cough
  - o blood in phlegm
  - o warm, red, or painful skin or sores on your body
  - o burning when you urinate or urinate more often than normal
  - o muscle aches
  - o shortness of breath
  - o weight loss
  - o diarrhea or stomach pain
  - o feeling very tired
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have diabetes, HIV-1 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, live, have lived, or traveled to certain countries where there is more risk for getting TB. Ask your healthcare provider if you are not sure.
- live, have lived, or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis). These infections may develop or become more severe if you receive CIMZIA. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B
- use the medicine Kineret® (anakinra), Orenicia® (abatacept), Rituxan® (rituximab), or Tysabri® (natalizumab)

### Stop using CIMZIA, and tell your healthcare provider right away if you have any of the symptoms of an infection listed above.

#### • Cancer.

- For people who receive TNF blockers, including CIMZIA, the chances of getting certain types of cancers may increase.
- Some children, teenagers, and young adults who received TNF blockers, including CIMZIA, have developed lymphoma and other certain types of rare cancers, some of which have caused death. These cancers are not usually seen in this age group. **CIMZIA is not for use in children.**
- People with inflammatory diseases, including rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis, especially those with very active disease, may be more likely to get lymphoma.
- Some people who receive TNF blockers, including CIMZIA, have developed a rare type of cancer which may cause death, called hepatosplenic T-cell lymphoma. Most of these people were male teenagers and young adult males with Crohn's disease or ulcerative colitis. Also, most of these people had been treated with *both* a TNF blocker *and* another medicine called IMURAN® (azathioprine) or PURINETHOL® (6-mercaptopurine, 6-MP).
- Some people who receive CIMZIA have developed certain types of skin cancer. Tell your healthcare provider if you develop any changes in the appearance of your skin, including growths on your skin, during or after treatment with CIMZIA. You should see your healthcare provider periodically during treatment for skin examinations, especially if you have a history of skin cancer.

## What is CIMZIA?

CIMZIA is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker used in adults 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)
- Treat active psoriatic arthritis (PsA)
- Treat active ankylosing spondylitis (AS)
- Treat active non-radiographic axial spondyloarthritis (nr-axSpA) with measures of inflammation
- Treat moderate to severe plaque psoriasis (PsO) in adults who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills)

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

### Before receiving CIMZIA, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- have or have had lymphoma or any other type of cancer
- have or had congestive heart failure

- have or have had seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis or Guillain-Barre syndrome.
- are scheduled to receive a vaccine. Do not receive a live vaccine while receiving CIMZIA.
- are allergic to certolizumab pegol or any of the ingredients in CIMZIA. See the Medication Guide for a complete list of the ingredients in CIMZIA.
- are pregnant or plan to become pregnant. You and your doctor should decide if you should continue to take CIMZIA while you are pregnant. It is not known if CIMZIA will harm your unborn baby. **Pregnancy Registry:** If you become pregnant during treatment with 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. Talk to your healthcare provider about the best way to feed your baby during treatment with CIMZIA.

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

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

### How will 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 on how to inject CIMZIA the right way. 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:

- 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.  
The plastic needle shield inside the removable cap of the prefilled syringe contains natural rubber and may cause an allergic reaction if you are sensitive to latex.
- **Hepatitis B virus reactivation in people who carry the virus in their blood.** In some cases, people who received CIMZIA have died because of the 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:
  - o feel unwell
  - o skin or eyes look yellow
  - o tiredness (fatigue)
  - o poor appetite or vomiting
  - o 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:
  - o dizziness
  - o numbness or tingling
  - o problems with your vision
  - o 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 does not go away, bruising or bleeding very easily, or looking very pale. Tell your healthcare provider right away if you have any bruising, bleeding or a fever that does not go away.
- **Immune reactions including a lupus-like syndrome.** Symptoms include shortness of breath, joint pain, or a rash on your 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, and urinary tract infections (bladder infections).

These are not all of the possible side effects of CIMZIA. Call your doctor for medical advice about side effects.

**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.**

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

