

To lessen signs and symptoms of moderate to severe **Crohn's Disease** in adults not helped enough by usual treatments

Important Safety Information About CIMZIA® (certolizumab pegol)

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

CIMZIA is a prescription 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 your 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.

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 or have signs of an infection such as fever, cough or flu-like symptoms or if you get a lot of infections or have infections that keep coming back.
- Have any open cuts or sores
- Have diabetes or 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
- Have congestive heart failure
- Have seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis

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- 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.
- Especially tell your doctor if you take: Kineret® (anakinra), Orencia® (abatacept), Rituxan® (rituximab), Tysabri® (natalizumab), or another TNF blocker. You have a higher chance for serious infections when taking CIMZIA with these medicines. You should not take CIMZIA while you take one of these medicines.

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; **Nervous System Problems** such as Multiple Sclerosis, seizures, or inflammation of the nerves of the eyes; **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; **Blood Problems**. Your body may not make enough of the blood cells that help fight infections or help stop bleeding; **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).

Other side effects have happened in some people including new psoriasis or worsening of psoriasis you already have and injection site reactions.

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

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