

DOCTOR DISCUSSION GUIDE



Talking About CIMZIA® (certolizumab pegol)

Your rheumatologist is a powerful ally in your battle against moderate to severe rheumatoid arthritis (RA), so it's important to work closely with him or her to ensure your RA treatment continues to be effective. If your RA symptoms are not well controlled, or you are having trouble with daily activities, changing treatments may help.

Is CIMZIA Right for You?

Whether you are considering starting or switching to a biologic treatment, you may want to ask your doctor if CIMZIA is an option for you. To help you start the conversation about CIMZIA with your doctor, here are some questions you can print and take to your next appointment:

1. Is now a good time for me to start taking a biologic medication for my RA?
2. What can you tell me about CIMZIA as an option for treating RA?
3. Am I a good candidate for trying CIMZIA?
4. Is there anything I need to do before I can start CIMZIA? Can I continue taking my other medications?
5. What are the risks and benefits of taking CIMZIA?
6. How common is injection site pain including stinging or burning with CIMZIA?
7. Can you show me the prefilled syringe and let me see how it feels in my hand?
8. I've read that CIMZIA can be taken every 2 weeks or every 4 weeks after initial dosing. Which dosing schedule would be right for me?
9. Can you give me more information about my options for taking CIMZIA at home or in the doctor's office?

Add your questions here:

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

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.

CIMZIA is used to treat adults with moderately to severely active RA.

Please refer to www.CIMZIA.com for the Medication Guide.

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
- 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 booklet called "Patient 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 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. Patients 65 years of age or older, patients with other long term medical conditions, or taking certain other drugs that affect the immune system, such as corticosteroids or methotrexate, may be at a greater risk of infection.

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). 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.