

It's important to be open and honest with your rheumatologist about the impact of your symptoms, to determine the right treatment for you.

cimzia[®]
(certolizumab pegol)

For Moderate-to-Severe
Non-Radiographic
Axial Spondyloarthritis

Print this guide to answer the questions below and help assess the full impact your condition has on various areas of your life. Then bring the results to your next appointment for a more productive conversation with your rheumatologist.

List any physical symptoms you are struggling to manage.

How do your symptoms impact your daily life? (Check all that apply)

- I think about it sometimes but feel good that symptoms are in check
- It affects my ability to work because of the debilitating pain
- I'm often in pain or tired, so I don't participate in activities like I used to
- I constantly rely on pain relievers, but they're not doing the job anymore
- My condition consumes my thoughts and I find myself adjusting my lifestyle to manage it
- Other _____

How does your inflammatory back pain make you feel? (Check all that apply)

- Confident that I don't let my condition define me
- Less confident than I should be
- Controlled by my painful symptoms
- Resigned to treatment that doesn't work
- Other _____

How would you rate the impact of your inflammatory back pain on your emotional well-being?

- Little to none
- Considerable
- Somewhat extreme
- Extreme
- Other _____

Does your condition hold you back from any of the following? (Check all that apply)

- My career goals
- My social life
- Enjoying romantic relationships
- Taking vacations
- Being present in the moment
- Other _____

Think about your current treatment to manage your symptoms. Is it giving you the results you had hoped for?

- No, I was hoping for better results from it
- No, but I am worried about making a change
- I am currently not on treatment for my inflammatory back pain
- Other _____

CIMZIA 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.

CIMZIA is approved for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with measures of inflammation.

Please see additional important safety information on reverse side and visit CIMZIA.com for full prescribing information.

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), Orencia® (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.

- o For people who receive TNF blockers, including CIMZIA, the chances of getting certain types of cancers may increase.
- o 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.
- o 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.
- o 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).
- o 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 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) in adults.
- Treat active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older.
- Treat active psoriatic arthritis (PsA) in adults.
- Treat active ankylosing spondylitis (AS) in adults.
- Treat active non-radiographic axial spondyloarthritis (nr-axSpA) with measures of inflammation in adults.
- 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).

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.
- are allergic to rubber or latex. The plastic needle shield inside the removable cap of the prefilled syringe contains natural rubber.

- 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.
- have or had serious blood conditions.
- are scheduled to receive a vaccine. Do not receive a live vaccine immediately before starting treatment with CIMZIA or 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.
- 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?

If your healthcare provider prescribes the CIMZIA powder, it should be injected by a healthcare provider. Each dose of CIMZIA will be given as 1 or 2 separate injections under the skin (subcutaneous injection) in your stomach area (abdomen) 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 instructions on how to inject CIMZIA the right way. Read the detailed Instructions for Use 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 prefilled syringe is given as an injection under the skin (subcutaneous injection) in your stomach area (abdomen) or upper thighs. 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. If you are prescribed more than 1 injection, each injection should be given at a different site in your stomach or upper thighs and at least 1 inch from your last injection. Make sure the solution in the CIMZIA prefilled syringe is clear to opalescent, and colorless to yellow and free from particles. **Do not use the CIMZIA prefilled syringe if the medicine is cloudy, discolored, or contains particles.**

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.** Get medical help right away if you have any signs of an allergic reaction which 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, or call 1-800-FDA-1088.

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