



Indications: CIMZIA (certolizumab pegol) is approved for the treatment of adults with moderate to severe active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), and active ankylosing spondylitis (AS). CIMZIA is also approved to lessen the signs and symptoms of moderate to severe active Crohn's disease (CD) in adults who have not been helped enough by usual treatments.

Please see the Important Safety Information and full Prescribing Information beginning on p. 6.

Frequently Asked Questions

Thank you for considering CIMZIA. When you're exploring a new treatment, there are always lots of great questions that need answers. We're here to help, and if you don't see the answer you need on this page, please contact your doctor or reach out to a CIMplicity® nurse at **1-844-UCBNurse (1-844-822-6877)**. We're available by phone Monday–Friday, 8 AM–8 PM, ET.

About CIMZIA

What are the possible side effects of CIMZIA?

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.

Other serious side effects can occur including certain types of cancers, heart failure, allergic reactions, reactivation of hepatitis B infection in carriers of the virus, nervous system problems, blood problems, and certain immune reactions including a lupus-like syndrome. The most common side effects of CIMZIA include upper respiratory infections, rash, and urinary tract infections. Talk to your doctor about other possible side effects and read the Medication Guide for CIMZIA.

How do biologic medications work?

As a biologic, CIMZIA is a drug derived from living sources that copy the effects of substances naturally made by your body's immune system. CIMZIA may lessen inflammation by blocking a substance called tumor necrosis factor (TNF) that may cause or worsen the inflammation.

How long does it take CIMZIA to work?

While every patient's experience is different, here are the general findings from clinical trials:

- ▶ **RA:** In clinical trials, CIMZIA provided noticeable relief from RA symptoms for the majority of patients within 24 weeks versus placebo. Some patients saw noticeable improvement in as fast as one to two weeks. Your results may vary.

- ▶ **PsA:** In a clinical trial versus placebo, CIMZIA was proven to provide noticeable PsA joint symptom relief within 12 weeks for the majority of patients and as fast as 1 to 2 weeks for some patients. Your results may vary. The majority of patients who had active skin involvement reported 75% skin improvement by 24 weeks.
- ▶ **AS:** In a clinical trial, CIMZIA was proven versus placebo to provide noticeable AS symptom relief, including improvements in morning stiffness, tenderness, and inflammatory back pain for the majority of patients after 12 weeks and for some as fast as one to two weeks. Your results may vary.
- ▶ **CD:** In a clinical trial, CIMZIA was proven versus placebo to provide noticeable CD symptom relief for the majority of patients who continued to take CIMZIA for 26 weeks of treatment. In another clinical trial, some patients had results in as fast as six weeks. Your results may vary.

When was CIMZIA approved by the FDA?

- ▶ CIMZIA was FDA-approved for adults with moderate to severe CD not helped enough by usual treatments in April 2008.
- ▶ CIMZIA was FDA-approved for adults with moderate to severe RA in 2009.
- ▶ CIMZIA was FDA-approved for adults with active PsA in September 2013.
- ▶ CIMZIA was FDA-approved for adults with active AS in October 2013.

Who makes CIMZIA?

CIMZIA is made by UCB, a global biopharmaceutical company. UCB is passionate about helping patients and their families with chronic severe diseases.

Is there a patient support program for CIMZIA?

Yes. CIMplicity^{®2} is a free support program designed for CIMZIA patients. CIMplicity offers services, information, tools, and resources to help you understand RA, PsA, AS, or CD and your treatment. Healthcare professionals are available to answer questions you have about CIMZIA. Sign up here or by calling **1-866-4-CIMZIA (1-866-424-6942)** and selecting option 2.

²The CIMplicity program is provided as a service of UCB and is intended to support the appropriate use of CIMZIA. The CIMplicity program may be amended or cancelled at any time without notice. Some program and eligibility restrictions may apply.

Taking CIMZIA and Dosing Schedules

How do I take CIMZIA?

CIMZIA is given as an injection just beneath the skin that you can give yourself or receive from a healthcare provider. If your doctor determines that you can give yourself shots, you will receive instructions, as well as nurse support from the CIMplicity® patient support program, on how to use a prefilled syringe, so you can inject CIMZIA at home or when you travel. You can also arrange to have a family member or friend obtain the training necessary to give you your injection. If you are not able to give yourself shots, your doctor or a nurse can administer CIMZIA in your doctor's office.

How many injections will I need and how often?

As you begin therapy, be sure to follow your doctor's instructions. There are 2 dosing phases for CIMZIA that your doctor may prescribe—starter dosing and maintenance dosing. Starter dosing covers your first month of injections, which are given at the start of treatment at week 0 (day 0), week 2 (day 14), and week 4 (day 28). Each of these doses is 400 mg given under the skin as 2 separate injections of 200 mg each. Reminder: Be sure to inject both syringes one right after the other at 2 different injection sites if prescribed 2 injections (400 mg).

After you complete your starter dosing, you can then begin your maintenance dosing. During maintenance, if you are being treated for moderate to severe rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis, CIMZIA can either be injected as one 200-mg injection every 2 weeks or two 200-mg injections every 4 weeks (or 28 days). If you are being treated for moderate to severe Crohn's disease, your maintenance schedule consists of two 200-mg injections every 4 weeks. You will receive complete dosing instructions from your doctor, which you should carefully follow when taking CIMZIA.

Can I receive injection training and support for the prefilled syringe?

Yes. Start by talking to your doctor. If you are beginning CIMZIA therapy and want to inject the CIMZIA prefilled syringe at home, you or a caregiver will receive the training you need at your doctor's office. Your other option is to choose to have a nurse come directly to your home, free of charge, to provide training through our CIMplicity® program². Our nurses can also provide training to a loved one or friend.

You can also watch an injection-training video if you want to refresh your knowledge about how to inject. You can always reference the "Instructions for Use" booklet, which is available with your CIMZIA prefilled syringe drug kit.

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How should I dispose of my used CIMZIA syringes with needles attached?

Ask your doctor what to do with your used CIMZIA syringes with needles attached. Your state or locality may have special laws or requirements about how to dispose of them properly. Also ask your doctor or pharmacist about how to get a puncture-proof container (a “sharps” container) that meets the requirements of your particular state or locality.

Sign up here for our CIMplicity® program² to request a free sharps container.

When your container is about two-thirds full, tape the lid closed and then dispose of the container as instructed by your doctor, nurse, or pharmacist. Do not throw the container in the trash or recycle. You can throw your used alcohol swabs in the trash unless you are instructed otherwise.

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

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How should I store CIMZIA?

CIMZIA should be stored in your refrigerator in its original carton between 36° to 46° Fahrenheit (2° to 8° Celsius). Protect CIMZIA from light. **Do not put CIMZIA in the freezer; it should never be frozen.**

Financial Assistance

Can I get help paying for CIMZIA?

You can receive services and support to help you start and stay on CIMZIA, including a financial assistance program that provides up to \$15,000 in annual savings toward out-of-pocket costs^a (eligibility restrictions and maximum limits apply). To find out more about the CIMplicity® Savings Program or request a savings card, call **1-866-4-CIMZIA**.

^aSavings Card Eligibility: Available to individuals with commercial prescription insurance coverage for CIMZIA. Not valid for prescriptions that are reimbursed, in whole or in part, under Medicare (including Medicare Part D), Medicaid, similar federal-or state-funded programs (including any state prescription drug assistance programs and the Government Health Insurance Plan available in Puerto Rico), or where otherwise prohibited by law. Product dispensed pursuant to program rules and federal and state laws. Claims should not be submitted to any public payor (ie, Medicare, Medicaid, Medigap, TRICARE, VA, and DoD) for reimbursement. The maximum annual benefit amount is \$15,000 per calendar year. The parties reserve the right to amend or end this program at any time without notice.

If you are uninsured, other financial assistance may be available. Call UCBCares toll free at 1-844-599-CARE (2273) for more information. The CIMplicity® program is provided as a service of UCB, Inc., and is intended to support the appropriate use of CIMZIA. Any CIMplicity program may be amended or canceled at any time without notice. Some program and eligibility restrictions apply. Please consult your doctor if you have any questions about your condition or treatment. 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.

UCB, Inc., is not liable for unintended or unauthorized use of the CIMplicity® Savings Card if it is lost or stolen.

What is the CIMplicity® Savings Program?

The CIMplicity® Savings Program provides savings support for your out-of-pocket costs for CIMZIA throughout your treatment. The CIMplicity® Savings Program is sponsored by UCB, and there is no cost to participate. Eligibility requirements and maximum limits apply.

Does the co-pay program cover both my CIMZIA prescription and doctor visits?

No, the CIMplicity® Savings Program CANNOT be used for medical co-pays, such as visits to the doctor's office. The program provides savings on your CIMZIA drug out-of-pocket expenses.

What if my pharmacy does not accept the CIMplicity® Savings Program?

If the pharmacy approved by your insurance company does not accept the CIMplicity® Savings Program, call **1-844-277-6853**.

Can I use the CIMplicity® Savings Program if I am uninsured?

The CIMplicity® Savings Program is available only to insured patients who meet the eligibility criteria.

Can I use the CIMplicity® Savings Program if I'm on Medicare, Medicaid, or other government-funded plan?

No. Due to current legal and eligibility restrictions, individuals covered under Medicare, Medicaid, or any other government-run program cannot participate in the CIMplicity® Savings Program.

Is there a patient assistance program for CIMZIA?

Yes, call **1-866-395-8366** regarding the Patient Assistance Program.

How do I take advantage of the CIMplicity® Savings Program?

When you register for the CIMplicity® patient support program on this website, you may also begin enrollment in the CIMplicity® Savings Program.² A CIMplicity® representative will contact you to complete this process.

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Do I need to sign up again at the end of the year? Do my co-pay numbers expire?

With the CIMplicity® Savings Program, your card number does not expire, and you do not need to sign up again at the end of the year. You will automatically be reenrolled, and your savings card will always be ready for use.

Important Safety Information

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 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.

You should not start receiving CIMZIA if you have any kind of infection unless your healthcare provider says it is okay.

Before you receive CIMZIA, tell your healthcare provider if you:

- think you have an infection, flu-like symptoms, or have any other symptoms of an infection such as:
 - fever, sweat, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in phlegm
 - weight loss
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinate more often than normal
 - feeling very tired
- are being treated for an infection, or get a lot of infections or have infections that keep coming back
- have diabetes, HIV, 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, lived in, or traveled to countries where there is more risk of getting TB. Ask your healthcare provider 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 healthcare provider.
- 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 healthcare provider right away. CIMZIA can make you more likely to get infections or make any infection that you may have worse.

Cancer

- For people taking TNF-blocker medicines, including CIMZIA, the chances of getting lymphoma or other cancers may increase.
- There have been cases of cancers in children, teenagers, and young adults who received TNF-blocker medicine that do not usually happen in people this age. CIMZIA is not approved for use in pediatric patients. People with RA, especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma.
- Some people receiving TNF-blocker medicines, including CIMZIA, have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. Most of these people were male teenagers and young males with Crohn's disease or ulcerative colitis. Also, most of these people had been treated with *both* a TNF-blocker medicine *and* another medicine called IMURAN® (azathioprine) or PURINETHOL® (6-mercaptopurine, 6-MP).
- If you use TNF-blocker medicine, including CIMZIA, your chance of developing certain kinds of skin cancer may increase. Tell your healthcare provider if any changes in the appearance of your skin, including growths on your skin, happen during or after your treatment.

What is CIMZIA?

CIMZIA is a prescription 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 patients 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)

What should I tell my healthcare provider before starting treatment with CIMZIA?

CIMZIA may not be right for you. Before starting CIMZIA, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- 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.
- are allergic to rubber or latex. 7% of the plastic needle shield inside the removable cap is derived from natural rubber latex.
- are pregnant or planning to become pregnant. Tell your healthcare provider right away if you become pregnant while receiving CIMZIA.

Pregnancy Registry: If you become pregnant while taking 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. You and your healthcare provider should decide if you will receive CIMZIA or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take the following medicines due to a higher chance for serious infections:

- Kineret® (anakinra), Orencia® (abatacept), Rituxan® (rituximab), or Tysabri® (natalizumab)
- medicines called Tumor Necrosis Factor (TNF) blockers, such as Remicade® (infliximab), Humira® (adalimumab), Enbrel® (etanercept), or Simponi® (golimumab)

Ask your healthcare provider if you are not sure. You should not take CIMZIA while you take any of these medicines.

How should 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 for complete instructions for use. 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:

- **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.
- **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 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.
- **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 healthcare provider right away if you have any side effects listed above.

The most common side effects of CIMZIA include: upper respiratory infections (flu, cold), rash, and urinary tract infections (bladder infections).

Tell your healthcare provider about any side effect that bothers you or does not go away. These are not all of the possible side effects of CIMZIA. For more information, ask your healthcare provider or pharmacist.

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.

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