



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. CIMZIA is approved to 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).

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?

**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.**

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 one to two 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.
- ▶ **PsO:** In clinical trials, CIMZIA was proven to provide noticeably clearer skin for the majority of patients within 16 weeks versus placebo, some as fast as four 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.
- ▶ CIMZIA was FDA-approved for adults with moderate to severe PsO in May 2018.

### 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<sup>2</sup> is a free support program designed for CIMZIA patients. CIMplicity offers services, information, tools, and resources to help you understand RA, PsA, AS, CD, or PsO and your treatment. Healthcare professionals are available to answer questions you may have about CIMZIA. Sign up at **CIMZIA.com** or by calling **1-866-4-CIMZIA (1-866-424-6942)** and selecting option 2.

<sup>2</sup>The 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 canceled 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.

## 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.

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.

## 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 for our CIMplicity program<sup>2</sup> 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.

<sup>2</sup>The 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 canceled at any time without notice. Some program and eligibility restrictions may apply.

## 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.** When necessary, CIMZIA syringes may be stored at room temperature up to 77°F (25°C) in the original carton to protect from light for a single period of up to 7 days. Once a CIMZIA syringe has been stored at room temperature, do not place it back in the refrigerator. Write the date removed from the refrigerator in the space provided on the carton and discard if not used within the 7-day period.

## 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<sup>1</sup> (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**.

**<sup>1</sup>Savings 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 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](http://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 any 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<sup>2</sup>. A CIMplicity representative will contact you to complete this process.

<sup>2</sup>The 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 canceled at any time without notice. Some program and eligibility restrictions may apply.

### **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 re-enrolled, 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 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 Kinerelex® (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.**

- 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 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 allergic to rubber or latex; 7% of the plastic needle shield inside the removable cap is derived from natural rubber latex.
- are pregnant or plan to become pregnant. Tell your healthcare provider right away if you become pregnant during treatment with CIMZIA.

**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.
- **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 tiredness (fatigue)
- o pain on the right side of your stomach (abdomen)
- o skin or eyes look yellow
- o poor appetite or vomiting
- **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 problems with your vision
  - o numbness or tingling
  - 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 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.**

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