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Certolizumab

# Certolizumab

**Pronunciation:** *SER-toe-LIZ-oo-mab* **Generic name:** certolizumab pegol

Brand name: Cimzia

Dosage form: injection for subcutaneous use

Drug class: TNF alfa inhibitors

Medically reviewed by Carmen Pope, BPharm. Last updated on Dec 9, 2024.

Uses Side effects Before taking Dosage What to avoid Interactions FAQ

# What is certolizumab pegol?

Certolizumab pegol (brand name Cimzia) is an injectable TNF blocker that may be used to treat Crohn's disease, rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, polyarticular juvenile idiopathic arthritis, and non-radiographic axial spondyloarthritis in certain patients. Certolizumab reduces inflammation and improves symptoms by blocking a protein called TNFα (tumor necrosis factor-alpha).

In autoimmune conditions, like Crohn's disease, rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, and non-radiographic axial spondyloarthritis, inflammation can be caused or worsened when TNF is released in the body. Certolizumab pegol (Cimzia) blocks TNFα which means there is less inflammation and symptoms of inflammatory conditions improve. Certolizumab belongs to the drug class TNF alfa inhibitors.

Certolizumab pegol was first FDA-approved on April 22, 2008, under the brand name Cimzia, for moderate to severe active Crohn's disease in adults who have an inadequate response to conventional therapy to reduce signs and symptoms of the disease and to maintain clinical response. Since then, it has also been approved for specific adult patients with rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, and non-radiographic axial spondyloarthritis. There is currently no Cimzia generic.

## What is certolizumab used for?

Certolizumab may be used to treat adults with:

- moderately to severely active Crohn's disease and to maintain clinical response in those who have had an
  inadequate response to conventional therapy
- moderately to severely active rheumatoid arthritis
- active psoriatic arthritis
- active ankylosing spondylitis
- active non-radiographic axial spondyloarthritis with objective signs of inflammation

• moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Certolizumab may be used to treat patients 2 years of age and older with

• active polyarticular juvenile idiopathic arthritis (pJIA)

# Certolizumab pegol side effects

**Common certolizumab side effects** may include rash, pain or burning when you urinate, and cold symptoms such as stuffy nose, sneezing, and a sore throat.

### Serious side effects

Get emergency medical help if you have signs of an **allergic reaction to certolizumab** such as hives, difficulty breathing, or swelling of your face, lips, tongue, or throat. 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. Do NOT use this medicine if you have had a serious hypersensitivity reaction to certolizumab pegol, Cimzia, latex, or any of the inactive ingredients in the preparations.

Certolizumab affects your immune system. **Serious and sometimes fatal infections** may occur during treatment with certolizumab. Certolizumab should not be initiated in patients with an active infection. Your healthcare provider will monitor you for infection during and after treatment, including serious fungal infections in those who live or travel to areas where mycoses are endemic.

- Your risk of infection may be higher if you have diabetes, HIV, a weak immune system, hepatitis B, chronic
  infections, if you use certain medications, or if you live in or travel to certain areas.
- Tell your doctor if you have signs of infection, such as fever, chills, cough, sweating, muscle pain, open sores or skin wounds, unusual tiredness, feeling short of breath, painful urination, diarrhea, or weight loss.

Certolizumab may increase your **risk of certain cancers**, including a rare fast-growing type of lymphoma that can be fatal. Call your doctor right away if you have any of these symptoms of lymphoma:

- · chest pain, cough, feeling short of breath
- swelling in your neck, under your arms, or in your groin (this swelling may come and go)
- fever, night sweats, itching, weight loss, feeling tired
- feeling full after eating only a small amount or
- pain in your upper stomach that may spread to your back or shoulder.

Certolizumab may increase your risk of developing **heart failure** or worsen preexisting heart failure. Stop using certolizumab and call your doctor at once if you develop shortness of breath, swelling of your ankles or feet, or sudden weight gain.

Reactivation of the Hepatitis B virus (HBV) has occurred in people who carry the virus in their blood and who are taking TNF blockers, such as certolizumab. In some cases, people have died. Your healthcare provider should monitor you for HBV before and during treatment. Tell your healthcare provider if you have any symptoms of HBV such as feeling unwell, yellow skin or eyes, tiredness (fatigue), poor appetite, vomiting, or 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 have been reported with certolizumab. Symptoms may include dizziness, numbness or tingling, problems with your vision, or weakness in your arms or legs.

Certolizumab may cause **blood problems**. Your body may not make enough of the blood cells that help fight infections or help stop bleeding. Tell your healthcare provider right away if you have any bruising, bleeding, or a fever that does not go away, or look very pale.

Immune reactions including a **lupus-like syndrome**, have been associated with certolizumab. Call your healthcare provider right away if you develop shortness of breath, joint pain, or a rash on the cheeks or arms that worsens with sun exposure.

Do not receive a "live" vaccine while you are being treated with certolizumab.

Certolizumab is not approved for use by anyone younger than 18 years old.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Certolizumab side effects (more detail)

# Related/similar drugs

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Otezla (apremilast) is used to treat plaque psoriasis, psoriatic arthritis, and oral ulcers ...

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Entyvio (vedolizumab) is used to treat ulcerative colitis (UC) and Crohn's

disease, reducing ...

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# Before taking this medicine

Do not use it if you are allergic to certolizumab, Cimzia, latex, or any inactive ingredients in the product. Tell your healthcare provider if you have symptoms of an infection such as fever, chills, cough, skin sores, shortness of breath, weight loss, diarrhea, or painful urination.

Tell your doctor if you have ever had tuberculosis, or if anyone in your household has tuberculosis. Also, tell your doctor if you have recently traveled. Tuberculosis and some fungal infections are more common in certain parts of the world, and you may have been exposed during travel.

Certolizumab may cause a rare type of lymphoma (cancer) of the liver, spleen, and bone marrow that can be fatal. This has occurred mainly in teenagers and young men with Crohn's disease or ulcerative colitis. However, anyone with an inflammatory autoimmune disorder may have a higher risk of lymphoma. Talk with your doctor about your own risk.

Tell your doctor if you have ever had:

- · a chronic infection
- hepatitis B (or if you are a carrier of the virus)
- · lymphoma or other types of cancer

- a blood cell disorder
- · congestive heart failure
- a seizure
- an allergy to latex
- numbness or tingling, or a nervous system disorder such as multiple sclerosis or
- if you are scheduled to receive any vaccines or have recently been vaccinated with BCG (Bacille Calmette-Guerin)
- · are pregnant or plan to become pregnant
- · are breastfeeding.

## Certolizumab and pregnancy

It is not known whether certolizumab will harm an unborn baby. Tell your doctor if you are pregnant. Your name may be listed on a pregnancy registry to track the effects of certolizumab on the baby.

## Certolizumab and breastfeeding

It may not be safe to breastfeed a baby while you are using this medicine. Ask your doctor about any risks.

Certolizumab pregnancy and breastfeeding warnings (more detail)

# How is certolizumab given?

Certolizumab is administered by subcutaneous (under the skin) injection. A healthcare provider can administer this or they can teach you how to use it yourself.

Read and carefully follow any Instructions for Use provided with your medicine. Do not use Certolizumab if you don't
understand all instructions for proper use. Ask your doctor or pharmacist if you have questions.

Certolizumab is usually given every 2 to 4 weeks. You may need to use more than 1 injection to get a full dose. Follow your doctor's dosing instructions very carefully.

- Prepare your injection only when you are ready to give it. Do not use it if the medicine looks cloudy, has changed colors, or has particles in it. Call your pharmacist for new medicine.
- Certolizumab can increase your risk of bleeding or infection by changing the way your immune system works. You
  will need frequent medical tests.
- Each prefilled syringe is for one use only. Throw away after one use, even if there is still medicine left inside.
- Use a needle and syringe only once and then place them in a puncture-proof "sharps" container. Follow state or local laws about how to dispose of this container. Keep it out of the reach of children and pets.

# Certolizumab dosing information

The recommended adult initial dosage of certolizumab is 400mg (given as two injections of 200mg) for all conditions. Continued dosing depends on the condition:

• Crohn's Disease: 400 mg initially and at Weeks 2 and 4. If a response occurs, follow with 400 mg every four weeks

- Rheumatoid Arthritis: 400 mg initially and at Weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered
- Psoriatic Arthritis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered
- Ankylosing Spondylitis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks
- Non-radiographic Axial Spondyloarthritis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks
- Plaque Psoriasis: 400 mg initially every other week. For some patients (with body weight ≤ 90 kg), a dose of 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week may be considered.

**Polyarticular Juvenile Idiopathic Arthritis** recommended dose patients 2 years of age and older) Dose is weight dependent, and given every other week:

- 10 kg (22 lbs) to less than 20 kg (44 lbs): 100 mg initially and at Weeks 2 and 4, followed by 50 mg every other week
- 20 kg (44 lbs) to less than 40 kg (88 lbs): 200 mg initially and at Weeks 2 and 4, followed by 100 mg every other week
- Greater than or equal to 40 kg (88 lbs): 400 mg initially and at Weeks 2 and 4, followed by 200 mg every other week

## General certolizumab dosing information

Certolizumab may be self-administered into the upper thigh or abdomen (but not within 2 inches [5cm]) of the belly button. A caregiver may also administer certolizumab into the back of your upper arm.

- · Rotate injection sites.
- Do not inject into skin that is tender, bruised, red, or hard.
- When a 400 mg dose is needed (given as 2 subcutaneous injections of 200 mg), injections should occur at separate sites in the thigh or abdomen.
- Detailed Certolizumab dosage information

# What happens if I miss a dose?

Call your doctor for instructions if you miss a dose of certolizumab.

# What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

# What should I avoid while receiving certolizumab?

Avoid injecting certolizumab into scars, stretch marks, or skin that is red, bruised, swollen, hard, or tender.

Ask your doctor before receiving any vaccine while you are being treated with Certolizumab.

Avoid being near people who are sick or have infections. Avoid activities that may increase your risk of bleeding or

injury. Use extra care to prevent bleeding while shaving or brushing your teeth.

# What other drugs will affect certolizumab?

Tell your healthcare provider about all your medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell them if you take:

- abatacept
- adalimumab
- anakinra
- etanercept
- golimumab
- infliximab
- natalizumab
- rituximab.

This list is not complete. Other drugs may interact with certolizumab, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Certolizumab drug interactions (more detail)

# Does certolizumab interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



# **Storage**

Keep certolizumab (Cimzia) in the refrigerator between 36°F to 46°F (2°C to 8°C) in its original carton to protect it from light. Do not freeze. Do not use it if it has expired. Check the expiration date on the prefilled syringe or carton.

The Cimzia prefilled syringe is made of glass. Do not drop or crush the syringe.

Keep out of the reach of children.

Remove the Cimzia syringe from the refrigerator and let it reach room temperature before injecting your dose.

Unopened prefilled syringes may also be stored at room temperature for up to 7 days, away from heat and light. Throw away any prefilled syringes not used within 7 days. Do not put them back in the refrigerator.

# Cimzia ingredients

The certolizumab brand name is Cimzia. Cimzia contains no preservatives.

## Cimzia lyophilized powder

Active ingredient: certolizumab pegol

Inactive ingredients: lactic acid, polysorbate, sucrose.

The powder is mixed with sterile Water for Injection.

# Cimzia prefilled syringe

Active ingredient: certolizumab pegol

Inactive ingredients: sodium acetate, sodium chloride, Water for Injection

## Who makes certolizumab?

UCB, Inc. makes Cimzia, the only brand of certolizumab currently available.

## Certolizumab Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

# Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for certolizumab.

Cimzia (certolizumab pegol) - UCB, Inc.

Formulation type	Strength
Pre-Filled Syringe	200 mg/mL
Single-Dose Vial	200 mg

View Cimzia information in detail.

# Frequently asked questions

• What are the new drugs for rheumatoid arthritis (RA)?

#### References

1. Cimzia Package Insert

## More about certolizumab

- · Check interactions
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## **Patient resources**

### Other brands

Cimzia

### **Professional resources**

• Certolizumab Pegol monograph

### Other brands

Cimzia

## Related treatment guides

- · Crohn's Disease, Maintenance
- · Ankylosing Spondylitis
- · Crohn's Disease
- · Crohn's Disease, Active

## **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

#### **DRUG STATUS**

**Availability** 

Rx Prescription only

# Pregnancy & Lactation Risk data available CSA Schedule\* N/A Not a controlled drug Approval History Drug history at FDA

## **User Reviews & Ratings**

6.8 / 10

93 Reviews

## **Images**

Cimzia (certolizumab) 200 mg lyophilized powder for injection

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