



PATIENT & CAREGIVER EDUCATION

Certolizumab Pegol

This information from Lexicomp® explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Cimzia; Cimzia (1 Syringe); Cimzia (2 Syringe); Cimzia-Starter

Brand Names: Canada

Cimzia (2 Pen); Cimzia (2 Syringe)

Warning

- This drug may raise the chance of infection, including severe infections. Sometimes severe infections have led to death. Most people who had these infections were taking other drugs to lower the immune system like methotrexate or steroid drugs. If you have any infection, are taking antibiotics now or in the recent past, or have had many infections, talk with your doctor.
- TB (tuberculosis) has been seen in patients started on this drug. These patients were exposed to TB in the past, but never got the infection. You will be tested to see if you have been exposed to TB before starting this drug.
- Lymphoma and other cancers have happened in people who take this drug or drugs like it. This has been deadly in some cases. Talk with the doctor.

What is this drug used for?

- It is used to treat Crohn's disease.
- It is used to treat ankylosing spondylitis.
- It is used to treat plaque psoriasis.
- It is used to treat some types of arthritis.

- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have an infection.
- If you have recently had a vaccine.
- If you are taking any of these drugs: Abatacept, adalimumab, anakinra, etanercept, golimumab, infliximab, natalizumab, rituximab, or tocilizumab.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you have a latex allergy, talk with your doctor. Some products have latex.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- If you have high blood sugar (diabetes), talk with your doctor. You may be more likely to get infections.
- Have your skin checked as you have been told by your doctor.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- If you have had hepatitis B before or carry the virus, this drug can cause the virus to become active. This can lead to very bad and sometimes deadly liver problems. You will be tested for hepatitis B before starting this drug. You will need to watch for signs of hepatitis while taking

this drug and for several months after stopping it. Talk with your doctor.

- Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.
- Do not get a weakened bacteria like BCG for bladder cancer while you use this drug. Talk with your doctor.
- If giving this drug to your child and your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.
- If you used this drug when you were pregnant, tell your baby's doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or

symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of lupus like a rash on the cheeks or other body parts, sunburn easy, muscle or joint pain, chest pain or shortness of breath, or swelling in the arms or legs.
- Severe dizziness or passing out.
- Lump in the armpit, groin, or neck.
- Pale skin.

- Call your doctor right away if you have a swollen gland, night sweats, shortness of breath, or weight loss without trying.
- Blood cell problems have happened, like aplastic anemia and a type of low white blood cell count. Tell your doctor right away if you feel very tired or weak or have a fever, chills, shortness of breath, any unexplained bruising or bleeding, or purple “splotches” on your skin.
- Certain types of skin cancer have happened in people taking this drug. Call your doctor right away if you have a change in color or size of a mole, or any new or changing skin lump or growth.
- Rarely, people using drugs like this one have had nervous system problems. Sometimes, these problems have not gone away. Call your doctor right away if you have a burning, numbness, or tingling feeling that is not normal; change in eyesight; dizziness; seizures; or weakness in your arms or legs.
- Heart failure has happened with this drug, as well as heart failure that has gotten worse in people who already have it. Tell your doctor if you have heart disease. Call your doctor right away if you have shortness of breath, a big weight gain, a heartbeat that is not normal, or swelling in the arms or legs that is new or worse.

- A rare type of cancer called hepatosplenic T-cell lymphoma (HSTCL) has happened with this drug and other drugs like it. These cases have been deadly. Almost all cases were in people who were using drugs like this one along with certain other drugs (azathioprine or mercaptopurine). Most of the time, this happened during treatment for Crohn's disease or ulcerative colitis. Also, most cases were in male teenagers or young males. Talk with the doctor.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Irritation where the shot is given.
- Signs of a common cold.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at

<https://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- It is given as a shot into the fatty part of the skin on the top of the thigh or the belly area.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- Wash your hands before and after use.
- Move the site where you give the shot with each shot.
- Do not give into skin that is irritated, bruised, red, infected, hard, or scarred.
- Do not use if the solution is cloudy, leaking, or has particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Inject at least 1 inch (2.5 cm) away from where the last dose was given. If your dose has more than 1 injection, give the injections into 2 different places at least 1 inch (2.5 cm) apart.
- Do not give into skin within 2 inches (5 cm) of the belly

button.

- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

Prefilled syringes:

- Before giving the shot, let it come to room temperature. Do not heat this drug.
- Throw syringe away after use. Do not use the same syringe more than one time.

Vials:

- If stored in a refrigerator, let this drug come to room temperature before using it. Leave it at room temperature for at least 30 minutes. Do not heat this drug.
- This drug must be mixed with sterile water before using. The sterile water that comes with this drug is meant for one use only. Throw away any part of the sterile water that is not used after one use.
- When making, do not shake vial.
- Use right away after mixing or you may store in a refrigerator for up to 24 hours.

- When ready to inject the mixed drug, it should be at room temperature. Do not leave any mixed drug at room temperature for more than 2 hours before using.
- Throw away any part of the opened vial not used after the shot is given.

What do I do if I miss a dose?

- Call your doctor to find out what to do.

How do I store and/or throw out this drug?

All products:

- Store in a refrigerator. Do not freeze.
- Store in the original container to protect from light.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

Prefilled syringes:

- Some products may be stored at room temperature for up to 7 days. Some may be stored at room temperature

for up to 10 days. Be sure you know how long your drug may be stored at room temperature. Write down the date you take this drug out of the refrigerator. If stored at room temperature and not used, throw this drug away.

- Do not put this drug back in the refrigerator after it has been stored at room temperature.

Vials:

- If needed, you may store at room temperature for up to 6 months. Write down the date you take this drug out of the refrigerator. If stored at room temperature and not used within 6 months, throw this drug away.
- Do not put this drug back in the refrigerator after it has been stored at room temperature.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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