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(For additional information see "Certolizumab pegol: Drug information")

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Brand Names: US

Cimzia; Cimzia Prefilled; Cimzia Starter Kit

Brand Names: Canada

Cimzia

Warning

- Very bad and sometimes deadly infections have happened in patients who take
 this drug. 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.
- This drug is not approved for use in children. 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 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.
- 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.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- If you have high blood sugar (diabetes), talk with your doctor. You may be more likely to get infections.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- Have your skin checked as you have been told by your doctor.
- If you have a latex allergy, talk with your doctor. Some products have latex.
- 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.
- A rare type of cancer called hepatosplenic T-cell lymphoma (HSTCL) has
 happened with this drug. These cases have been deadly. Most of the time,
 these cases happened in teenagers or young adults. Most of these patients
 were using this drug to treat certain types of bowel problems like Crohn
 disease and ulcerative colitis. This drug is not approved for use to treat bowel
 problems like these. Tell the doctor if you have ever had any type of cancer. Talk
 with the doctor.
- 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.
- 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 breastfeeding. 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, feeling tired, not hungry, 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.
- Very bad 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.

- Unsafe blood cell count 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.

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.

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, 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 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 apart.
- Do not give into skin within 2 inches 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:

- If needed, you may store at room temperature for up to 7 days. Write down the date you take this drug out of the refrigerator. If stored at room temperature and not used within 7 days, 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.
- 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.

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Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine. The use of this information is governed by the Lexicomp End User License Agreement, available at

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