

17 PATIENT COUNSELING INFORMATION

See Medication Guide (17.2).

17.1 Patient Counseling

Advise patients of the potential risks and benefits of CIMZIA therapy. Give patients the Medication Guide and allow them time to read it prior to starting CIMZIA therapy and to review it periodically. Any questions resulting from the patient's reading of the Medication Guide should be discussed. Because caution should be exercised in administering CIMZIA to patients with clinically important active infections, advise patients of the importance of informing their health care providers about all aspects of their health at each treatment visit.

- **Immunosuppression**

Inform patients that CIMZIA may lower the ability of the immune system to fight infections. Instruct patients of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis and reactivation of hepatitis B virus infections.

Counsel patients about the possible risk of lymphoma and other malignancies while receiving CIMZIA.

- **Allergic Reactions**

Advise patients to seek immediate medical attention if they experience any symptoms of severe allergic reactions.

- **Other Medical Conditions**

Advise patients to report any signs of new or worsening medical conditions such as heart disease, neurological disease, or autoimmune disorders. Advise patients to report promptly any symptoms suggestive of a cytopenia such as bruising, bleeding, or persistent fever.

17.2 Medication Guide

MEDICATION GUIDE
CIMZIA® (CIM-zee-uh)
(certolizumab pegol)

Read the Medication Guide that comes with CIMZIA before you receive the first treatment, and before each time you get a treatment of CIMZIA. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

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, including tuberculosis (TB) have happened in patients taking CIMZIA. Some patients have died from these infections.

- Your doctor should test you for TB before starting CIMZIA.

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- Your doctor should monitor you closely for signs and symptoms of TB during treatment with CIMZIA.

Before starting CIMZIA, tell your doctor if you:

- think you have an infection
- are being treated for an infection
- have signs of an infection, such as a fever, cough, flu-like symptoms
- have any open cuts or sores on your body
- get a lot of infections or have infections that keep coming back
- have diabetes
- have HIV
- have tuberculosis (TB), or have been in close contact with someone with TB
- have or have had hepatitis B
- use the medicine Kineret® (anakinra)

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 doctor right away. CIMZIA can make you more likely to get infections or make any infection that you may have worse.

What is CIMZIA?

CIMZIA is a medicine called a Tumor Necrosis Factor (TNF) blocker. CIMZIA is used to reduce the signs and symptoms of moderately to severely active Crohn's disease in adult patients who have not been helped enough by usual treatments.

What should I tell my doctor before starting treatment with CIMZIA?

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

- **have an infection.** (See, 'What is the most important information I should know about CIMZIA?')
- **have or have had any type of cancer.**
- **have seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis**
- **have heart failure**
- **are scheduled to receive a vaccine.** Do not receive a live vaccine while taking CIMZIA.

Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. CIMZIA has not been studied in pregnant or nursing women.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Your doctor will tell you if it is okay to take your other medicines while taking CIMZIA. Especially, tell your doctor if you take:

- Kineret® (anakinra). You have a higher chance for serious infections when taking CIMZIA with Kineret®.

How should I receive CIMZIA?

- CIMZIA should be injected by a healthcare provider. Each dose of CIMZIA will be given as two separate injections under the skin in your stomach area (abdomen) or upper leg (thigh).
- Make sure to keep all of your injection and follow-up appointments with your doctor.

What are the possible side effects of CIMZIA?

Serious side effects have happened in patients taking CIMZIA including:

- **Serious infections including tuberculosis (TB).** See “What is the most important information I should know about CIMZIA?”
- **Cancer including lymphoma.**
- **Nervous System Problems** such as Multiple Sclerosis, seizures, or inflammation of the nerves of the eyes. Symptoms include dizziness, numbness or tingling, problems with your vision, and weakness in your arms or legs.
- **Allergic Reactions.** Signs of an allergic reaction include a skin rash, swollen face, or trouble breathing.
- **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 doesn't go away, bruising or bleeding very easily, or looking very pale.
- **Heart Failure** including new heart failure or worsening of heart failure you already have. Symptoms include shortness of breath, or swelling of your ankles or feet.
- **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 doctor right away if you develop any of the above side effects or symptoms.

The most common side effects of CIMZIA are:

- upper respiratory infections (flu, cold)
- urinary tract infections (bladder infections)
- joint pain

Injection site reactions happen in some people.

Tell your doctor about any side effect that bothers you or does not go away.

These are not all of the side effects with CIMZIA. Ask your doctor or pharmacist for more information.

General information about CIMZIA

Cimzia®
(certolizumab pegol)

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Medicines are sometimes prescribed for purposes that are not mentioned in Medication Guides. Do not use CIMZIA for a condition for which it was not prescribed. Do not give CIMZIA to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about CIMZIA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about CIMZIA that is written for health professionals.

For more information go to www.CIMZIA.com or call 1-866-822-0068.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What are the ingredients in CIMZIA?

The active ingredient is certolizumab pegol.

The inactive ingredients in CIMZIA include: sucrose, lactic acid, polysorbate. No preservatives are present.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Product developed and manufactured for:

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