

MEDICATION GUIDE
CYLTEZO® (sil-TEE-zoh)
(adalimumab-adbm)

injection, for subcutaneous use

Read the Medication Guide that comes with CYLTEZO before you start taking it and each time you get a refill. There may be new information. 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 CYLTEZO?

CYLTEZO is a medicine that affects your immune system. CYLTEZO can lower the ability of your immune system to fight infections. **Serious infections have happened in people taking adalimumab products. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi or bacteria that have spread throughout the body. Some people have died from these infections.**

- Your doctor should test you for TB before starting CYLTEZO.
- Your doctor should check you closely for signs and symptoms of TB during treatment with CYLTEZO.

You should not start taking CYLTEZO if you have any kind of infection unless your doctor says it is okay.

Before starting CYLTEZO, tell your doctor if you:

- think you have an infection or have symptoms of infection such as:
 - fever, sweats, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in phlegm
 - warm, red or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinate more often than normal
 - feel very tired
 - weight loss
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes.
- have TB, or have been in close contact with someone with TB.
- were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure.
- live or have lived in certain parts of the country (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis). These infections may happen or become more severe if you use CYLTEZO. Ask your doctor 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 ORENCIA® (abatacept), KINERET® (anakinra), RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (6-mercaptopurine, 6-MP).
- are scheduled to have major surgery.

After starting CYLTEZO, call your doctor right away if you have an infection, or any sign of an infection.

CYLTEZO can make you more likely to get infections or make any infection that you may have worse.

Cancer

- For children and adults taking Tumor Necrosis Factor (TNF)-blockers, including CYLTEZO, the chances of getting cancer may increase.
- There have been cases of unusual cancers in children, teenagers, and young adults using TNF-blockers.
- People with rheumatoid arthritis (RA), especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma.
- If you use TNF blockers including CYLTEZO your chance of getting two types of skin cancer may increase (basal cell cancer and squamous cell cancer of the skin). These types of cancer are generally not life-threatening if treated. Tell your doctor if you have a bump or open sore that does not heal.
- Some people receiving TNF blockers, such as CYLTEZO developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. Most of these people were male teenagers or young men. Also, most people were being treated for Crohn's disease or ulcerative colitis with another medicine called IMURAN® (azathioprine) or PURINETHOL® (6-mercaptopurine, 6-MP).

What is CYLTEZO?

CYLTEZO is a medicine called a Tumor Necrosis Factor (TNF) blocker. CYLTEZO is used:

- To reduce the signs and symptoms of:
 - **moderate to severe rheumatoid arthritis (RA) in adults.** CYLTEZO can be used alone, with methotrexate, or with certain other medicines.
 - **moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children 4 years and older.** CYLTEZO can be used alone, with methotrexate, or with certain other medicines.

- **psoriatic arthritis (PsA) in adults.** CYLTEZO can be used alone or with certain other medicines.
- **ankylosing spondylitis (AS) in adults.**
- **moderate to severe Crohn's disease (CD) in adults** when other treatments have not worked well enough.
- In adults, to help get **moderate to severe ulcerative colitis (UC)** under control (induce remission) and keep it under control (sustain remission) when certain other medicines have not worked well enough. It is not known if CYLTEZO is effective in people who stopped responding to or could not tolerate TNF-blocker medicines.
- **To treat moderate to severe chronic (lasting a long time) plaque psoriasis (Ps) in adults** who have the condition in many areas of their body and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).

What should I tell my doctor before taking CYLTEZO?

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

- have an infection. See **“What is the most important information I should know about CYLTEZO?”**
- have or have had cancer.
- have any numbness or tingling or have a disease that affects your nervous system such as multiple sclerosis or Guillain-Barré syndrome.
- have or had heart failure.
- have recently received or are scheduled to receive a vaccine. You may receive vaccines, except for live vaccines while using CYLTEZO. Children should be brought up to date with all vaccines before starting CYLTEZO.
- are allergic to rubber or latex. The needle cap on the prefilled syringe contains dry natural rubber or latex. Tell your doctor if you have any allergies to rubber or latex.
- are allergic to CYLTEZO or to any of its ingredients. See the end of this Medication Guide for a list of ingredients in CYLTEZO.
- are pregnant or plan to become pregnant. It is not known if CYLTEZO will harm your unborn baby. CYLTEZO should only be used during a pregnancy if needed.
- have a baby and you were using CYLTEZO during your pregnancy. Tell your baby's doctor before your baby receives any vaccines.
- breastfeeding or plan to breastfeed. You and your doctor should decide if you will breastfeed or use CYLTEZO. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your doctor if you use:

- ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol) or SIMPONI® (golimumab), because you should not use CYLTEZO while you are also using one of these medicines.
- RITUXAN® (rituximab). Your doctor may not want to give you CYLTEZO if you have received RITUXAN® (rituximab) recently.
- IMURAN® (azathioprine) or PURINETHOL® (6-mercaptopurine, 6-MP).

Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take CYLTEZO?

- CYLTEZO is given by an injection under the skin. Your doctor will tell you how often to take an injection of CYLTEZO. This is based on your condition to be treated. **Do not inject CYLTEZO more often than you were prescribed.**
- See the **Instructions for Use** inside the carton for complete instructions for the right way to prepare and inject CYLTEZO.
- Make sure you have been shown how to inject CYLTEZO before you do it yourself. You can call your doctor or 1-800-542-6257 if you have any questions about giving yourself an injection. Someone you know can also help you with your injection after they have been shown how to prepare and inject CYLTEZO.
- **Do not** try to inject CYLTEZO yourself until you have been shown the right way to give the injections. If your doctor decides that you or a caregiver may be able to give your injections of CYLTEZO at home, you should receive training on the right way to prepare and inject CYLTEZO.
- Do not miss any doses of CYLTEZO unless your doctor says it is okay. If you forget to take CYLTEZO, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. This will put you back on schedule. In case you are not sure when to inject CYLTEZO, call your doctor or pharmacist.
- If you take more CYLTEZO than you were told to take, call your doctor.

What are the possible side effects of CYLTEZO?

CYLTEZO can cause serious side effects, including:

See “What is the most important information I should know about CYLTEZO?”

- **Serious Infections.** Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with CYLTEZO and during treatment with CYLTEZO. Even if your TB test is negative your doctor should carefully monitor you for TB

infections while you are taking CYLTEZO. People who had a negative TB skin test before receiving adalimumab products have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking CYLTEZO:

- cough that does not go away
- low grade fever
- weight loss
- loss of body fat and muscle (wasting)
- **Hepatitis B infection in people who carry the virus in their blood.** If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use CYLTEZO. Your doctor should do blood tests before you start treatment, while you are using CYLTEZO, and for several months after you stop treatment with CYLTEZO. Tell your doctor if you have any of the following symptoms of a possible hepatitis B infection:
 - muscle aches
 - feel very tired
 - dark urine
 - skin or eyes look yellow
 - little or no appetite
 - vomiting
 - clay-colored bowel movements
 - fever
 - chills
 - stomach discomfort
 - skin rash
- **Allergic reactions.** Allergic reactions can happen in people who use CYLTEZO. Call your doctor or get medical help right away if you have any of these symptoms of a serious allergic reaction:
 - hives
 - trouble breathing
 - swelling of your face, eyes, lips or mouth
- **Nervous system problems.** Signs and symptoms of a nervous system problem include: numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- **Blood problems.** Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **New heart failure or worsening of heart failure you already have. Call your doctor right away** if you get new worsening symptoms of heart failure while taking CYLTEZO, including:
 - shortness of breath
 - sudden weight gain
 - swelling of your ankles or feet
- **Immune reactions including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on your cheeks or arms that gets worse in the sun. Symptoms may improve when you stop CYLTEZO.
- **Liver problems.** Liver problems can happen in people who use TNF-blocker medicines. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms:
 - feel very tired
 - poor appetite or vomiting
 - skin or eyes look yellow
 - pain on the right side of your stomach (abdomen)
- **Psoriasis.** Some people using adalimumab products had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus. Your doctor may decide to stop your treatment with CYLTEZO.

Call your doctor or get medical care right away if you develop any of the above symptoms. Your treatment with CYLTEZO may be stopped.

Common side effects with CYLTEZO include:

- injection site reactions: redness, rash, swelling, itching, or bruising. These symptoms usually will go away within a few days. Call your doctor right away if you have pain, redness or swelling around the injection site that does not go away within a few days or gets worse.
- upper respiratory infections (including sinus infections)
- headaches
- rash

These are not all the possible side effects with CYLTEZO. Tell your doctor if you have any side effect that bothers you or that does not go away. Ask your doctor or pharmacist for more information.

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

How should I store CYLTEZO?

- Store CYLTEZO in the refrigerator at 36°F to 46°F (2°C to 8°C). Store CYLTEZO in the original carton until use to protect it from light.
- **Do not freeze CYLTEZO.** Do not use CYLTEZO if frozen, even if it has been thawed.
- Refrigerated CYLTEZO may be used until the expiration date printed on the CYLTEZO carton, dose tray, or prefilled syringe. Do not use CYLTEZO after the expiration date.
- If needed, for example when you are traveling, you may also store CYLTEZO at room temperature up to 77°F (25°C) for up to 14 days. Store CYLTEZO in the original carton until use to protect it from light.
- Throw away CYLTEZO if it has been kept at room temperature and not been used within 14 days.
- Record the date you first remove CYLTEZO from the refrigerator in the spaces provided on the carton and dose tray.
- Do not store CYLTEZO in extreme heat or cold.

- Do not use a prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it.
- Do not drop or crush CYLTEZO. The prefilled syringe is glass.

Keep CYLTEZO, injection supplies, and all other medicines out of the reach of children.

General information about the safe and effective use of CYLTEZO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CYLTEZO for a condition for which it was not prescribed. Do not give CYLTEZO to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about CYLTEZO. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about CYLTEZO that is written for health professionals. For more information go to www.cyltezo.com or call 1-800-542-6257.

What are the ingredients in CYLTEZO?

Active ingredient: adalimumab-adbm

CYLTEZO 40 mg/0.8 mL prefilled syringe and CYLTEZO 20 mg/0.4 mL prefilled syringe:

Inactive ingredients: glacial acetic acid, polysorbate 80, sodium acetate trihydrate, trehalose dihydrate, and Water for Injection.

Manufactured by: Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA

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For more information about CYLTEZO, go to www.cyltezo.com, or scan the code. You may also call 1-800-542-6257 or (TTY) 1-800-459-9906 for further information about CYLTEZO.



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

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