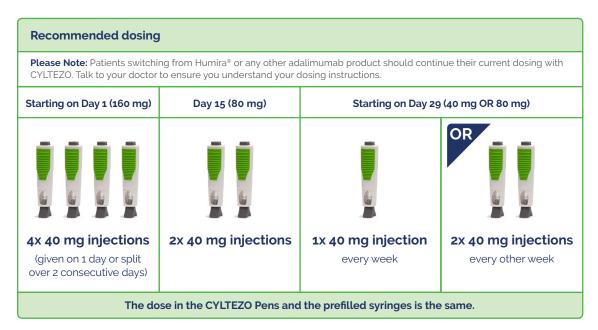


CYLTEZO is a medicine called a tumor necrosis factor (TNF) blocker. CYLTEZO is used to reduce the signs and symptoms of **moderate to severe hidradenitis suppurativa (HS) in adults**.

# CYLTEZO recommended dosing schedule for HS

The recommended starting dose on Day 1 for adults is **160 mg** by injection under the skin, **80 mg** on Day 15, and **40 mg** every week starting on Day 29 OR **80 mg** every other week starting on Day 29.

You may be prescribed either the CYLTEZO Pen or prefilled syringe. Your doctor will tell you how often to take an injection of CYLTEZO. Do not inject CYLTEZO more often than you were prescribed. It is important to talk with your doctor to ensure that you understand your CYLTEZO dosing instructions and refer to the <u>Medication Guide</u> for additional information about dosing.





This video is intended to provide an overview of the CYLTEZO Pen and does not replace the **Instructions for Use**. Please review the **Instructions for Use** with your doctor prior to performing your injection.

#### **Important Safety Information**

Serious infections have happened in patients 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. CYLTEZO may increase the chance of getting lymphoma, including a rare kind, or other cancers. CYLTEZO can cause serious side effects, including hepatitis B infection in carriers of the virus; allergic reactions; nervous system problems; blood problems; heart failure; certain immune reactions, including a lupus-like syndrome; liver problems; and new or worsening psoriasis.

Please see additional Important Safety Information, including the Indications, on pages 2-3 and the Medication Guide and Instructions for Use.

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#### Common side effects

The most common side effects of CYLTEZO include injection site reactions, upper respiratory infections (including sinus infections), headaches, and rash. The symptoms of injection site reactions such as redness, rash, swelling, itching, or bruising 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.

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.

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.

#### Important Safety Information for CYLTEZO® (adalimumab-adbm) injection, for subcutaneous use

# What is the most important information I should know about CYLTEZO?

You should discuss the potential benefits and risks of CYLTEZO with your doctor. CYLTEZO is a TNF-blocker medicine that can lower the ability of your immune system to fight infections. You should not start taking CYLTEZO if you have any kind of infection unless your doctor says it is okay.

- 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 and check you closely for signs and symptoms of TB during treatment with CYLTEZO, even if your TB test was negative. If your doctor feels you are at risk, you may be treated with medicine for TB.
- Cancer. For children and adults taking TNF blockers, including CYLTEZO, the chances of getting lymphoma or other cancers may increase. There have been cases of unusual cancers in children, teenagers, and young adults using TNF blockers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. If using TNF blockers, including CYLTEZO, your chances of getting two types of skin cancer (basal cell and squamous cell) may increase. These types are generally not life-threatening if treated; tell your doctor if you have a bump or open sore that doesn't heal.

### What should I tell my doctor BEFORE starting CYLTEZO?

Tell your doctor about all of your health conditions, including if you:

- Have an infection, are being treated for infection, or have symptoms of 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, or were born in, lived in, or traveled where there is more risk for getting TB.
- Live or have lived in an area (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections, such as histoplasmosis, coccidioidomycosis, or blastomycosis. These infections may happen or become more severe

if you use CYLTEZO. Ask your doctor if you are unsure whether you have lived in an area where these infections are common.

- Have or have had hepatitis B.
- Are scheduled for major surgery.
- Have or have had cancer.
- Have numbness or tingling or a nervous system disease such as multiple sclerosis or Guillain-Barré syndrome.
- Have or had heart failure.
- Have recently received or are scheduled to receive a vaccine. CYLTEZO
  patients may receive vaccines, except for live vaccines. Children
  should be brought up to date on all vaccines before starting CYLTEZO.
- Are allergic to rubber or latex.
- Are allergic to any CYLTEZO ingredients.
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed.
- Have a baby and you were using CYLTEZO during your pregnancy. Tell your baby's doctor before your baby receives any vaccines.

Also tell your doctor about all the medicines you take. You should not take CYLTEZO with ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol), or SIMPONI® (golimumab). Tell your doctor if you have ever used RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (mercaptopurine, 6-MP).

#### What should I watch for AFTER starting CYLTEZO?

**CYLTEZO** can cause serious side effects, including:

- **Serious infections.** These include TB and infections caused by viruses, fungi, or bacteria. Symptoms related to TB include a cough, low-grade fever, weight loss, or loss of body fat and muscle.
- Hepatitis B infection in carriers of the virus. Symptoms
  include muscle aches, feeling very tired, dark urine, skin or eyes
  that look yellow, little or no appetite, vomiting, clay-colored bowel
  movements, fever, chills, stomach discomfort, and skin rash.



Please see additional Important Safety Information, including the Indication, on page 3 and the <u>Medication Guide</u> and <u>Instructions for Use</u>.

### Important Safety Information for CYLTEZO® (adalimumab-adbm) injection, for subcutaneous use (continued)

## What should I watch for AFTER starting CYLTEZO? (continued)

- **Allergic reactions.** Symptoms of a serious allergic reaction include hives; trouble breathing; and swelling of your face, eyes, lips, or mouth.
- Nervous system problems. Signs and symptoms include numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- Blood problems (decreased blood cells that help fight infections or stop bleeding). Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- Heart failure (new or worsening). Symptoms include shortness of breath, swelling of your ankles or feet, and sudden weight gain.
- Immune reactions, including a lupus-like syndrome. Symptoms
  include chest discomfort or pain that does not go away, shortness
  of breath, joint pain, or rash on your cheeks or arms that gets
  worse in the sun.
- Liver problems. Symptoms include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of your stomach (abdomen). These problems can lead to liver failure and death.
- **Psoriasis** (new or worsening). Symptoms include red scaly patches or raised bumps that are filled with pus.

Call your doctor or get medical care right away if you develop any of the above symptoms.

The most common side effects of CYLTEZO include injection site reactions (pain, redness, rash, swelling, itching, or bruising), upper respiratory infections (sinus infections), headaches, and 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.

Please see the Medication Guide and Instructions for Use.

Remember to tell your doctor right away if you have an infection or symptoms of an infection, including:

- 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
- Urinating more often than normal
- Feeling very tired
- Weight loss

These are not all the possible side effects of CYLTEZO. For more information, speak with your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

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#### 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 hidradenitis suppurativa (HS) in adults.

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