



Your journey with IBD

Living with inflammatory bowel disease (IBD) can limit what you're able to do, especially when symptoms pop up.

Getting better means relief of symptoms and achieving remission. Remission is when your symptoms get much better or even go away completely.

To manage IBD symptoms and achieve remission, it's important to take medicine over the long term.

IBD is a broad term that describes conditions caused by inflammation of the gut. The 2 most common IBD diseases are Crohn's disease (CD) and ulcerative colitis (UC).

Crohn's disease can affect any part of your digestive tract, from the mouth to the anus, while **ulcerative colitis** involves inflammation of the large intestine or colon.

Common symptoms of both diseases include diarrhea, belly pain and cramps, and urgent bowel movements.



ZYMFENTRA fits the way you live

IBD treatment should keep your symptoms under control. With medical treatments given at an infusion center or doctor's office, there's the need to travel back and forth to appointments, take time off from school or work, and fit ongoing treatments into your already busy schedule. Over time, these challenges can really add up.

ZYMFENTRA™ has helped many patients achieve remission from the comfort of home, once their doctor determined it was appropriate and they, or their caregiver, received subcutaneous injection training.

Important Safety Information

What is the most important information I should know about ZYMFENTRA? ZYMFENTRA may cause serious side effects, including risk of infection and cancer.

• *Risk of infection:* ZYMFENTRA can lower the ability of your immune system to fight infections. Serious infections have happened in patients receiving ZYMFENTRA. These infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients have died from these infections.

Please see Important Safety Information on pages 14-17.

What to know about ZYMFENTRA

ZYMFENTRA™ is for adults with moderately to severely active ulcerative colitis or moderately to severely active Crohn's disease. It is given after an initial period of infliximab treatment delivered by intravenous (IV) infusion.

With approval from your doctor and subcutaneous injection training, you or your caregiver can administer ZYMFENTRA at home.

ZYMFENTRA Prefilled Pen



Important Safety Information

- Risk of infection (continued):
 - Your doctor should test you for TB before starting ZYMFENTRA, and should monitor you closely for signs and symptoms
 of TB during treatment.
 - If you have 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. ZYMFENTRA can make you more likely to get infections or make any infection that you have worse.

Enjoy greater freedom. From home.



Imagine not having to travel to an infusion center or doctor's office every time you need your IBD treatment. That's a major benefit of ZYMFENTRA.

Talk with your doctor about whether ZYMFENTRA is right for you. If you are prescribed ZYMFENTRA, you can shift from receiving infliximab at an infusion center to receiving maintenance treatment by injection. If your doctor decides that you or your caregiver can give your injections of ZYMFENTRA at home, a healthcare professional will show you the right way to prepare and self-inject ZYMFENTRA.

Benefits of long-term at-home injections



Convenience of at-home administration



No infusions



Less administration time



No need to schedule time off from work or school for administration

Please see Important Safety Information on pages 14-17.

New to infliximab treatment?

How to START—and STAY on treatment

There are 2 phases to your treatment:



START PHASE

There is a starting period to your treatment journey where you will be given medicine at an infusion center or doctor's office. The medicine you'll receive is the same type of medicine as ZYMFENTRA, only given intravenously, which means it is delivered into a vein in your arm. You will receive this medicine 3 times over 6 weeks.

WHAT TO EXPECT:

- · A doctor or nurse will be there to check on you while the medicine is given into a vein in your arm
- You will be seated comfortably the whole time. The entire appointment may take several hours from the time you arrive to when you leave
- After your first appointment, you will return at Weeks 2 and 6 to receive your next 2 doses

Important Safety Information

- *Risk of cancer:* There have been cases of unusual cancers in children and teenage patients using tumor necrosis factor (TNF) blocker medicines, such as ZYMFENTRA.
 - For people receiving TNF blocker medicines, the chances of getting lymphoma or other cancers may increase.
 - Some people receiving TNF blockers 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 a TNF blocker and another medicine called azathioprine or 6-mercaptopurine.

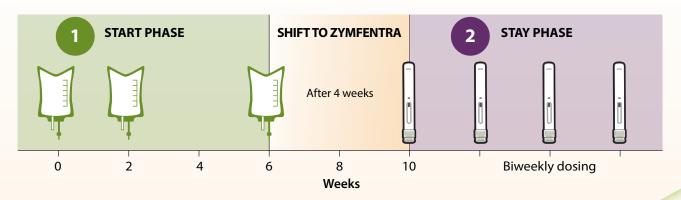


2 STAY PHASE

Four weeks after your last infusion appointment, and upon approval by your doctor, you can SHIFT to injecting ZYMFENTRA™ every 2 weeks from the comfort of home.

ZYMFENTRA is a subcutaneous injection. This means it is injected just below the skin, <u>not</u> into a vein, so you can safely inject it yourself or with the help of a caregiver. Do not inject ZYMFENTRA without first receiving training from a healthcare professional and reviewing the Instructions for Use.

The good thing about the STAY PHASE is, you're getting the same type of medicine as in the START PHASE—just in a more convenient delivery form.



Please see Important Safety Information on pages 14-17.

Already receiving maintenance treatment with IV infliximab?

How to SHIFT to treatment with ZYMFENTRA

There are 2 phases to your treatment:



CURRENT PHASE

If you are already responding well to ongoing treatment with infliximab given at an infusion center or doctor's office, it is easy to make the shift to $ZYMFENTRA^{TM}$.

Important Safety Information

- Risk of cancer (continued):
 - People who have been treated for Crohn's disease or ulcerative colitis for a long time may be more likely to develop lymphoma.
 This is especially true for people with very active disease.
 - Some people treated with infliximab products have developed certain kinds of skin cancer. If any changes in the appearance
 of your skin or growths on your skin occur during or after your treatment, tell your doctor.
 - Patients with chronic obstructive pulmonary disease (COPD), a specific type of lung disease, may have an increased risk for getting cancer while being treated with ZYMFENTRA.

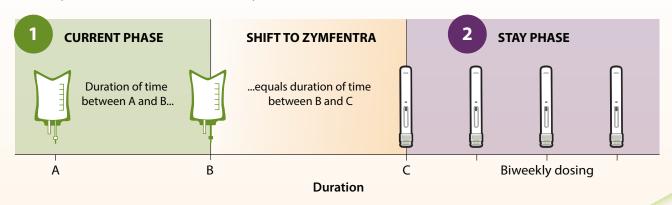


2 STAY PHASE

After your last infusion appointment, and upon approval by your doctor, you can SHIFT to injecting ZYMFENTRA every 2 weeks from the comfort of home.

ZYMFENTRA is a subcutaneous injection. This means it is injected just below the skin, <u>not</u> into a vein, so you can safely inject it yourself or with the help of a caregiver. Do not inject ZYMFENTRA without first receiving training from a healthcare professional and reviewing the Instructions for Use.

The good thing about the STAY PHASE is, you're getting the same type of medicine as in the START PHASE—just in a more convenient delivery form.



Please see Important Safety Information on pages 14-17.

The 4 Ps of injecting ZYMFENTRA

- 1 PREPARE for injection.
 - Gather your supplies
 - Remove the carton containing the prefilled pen from the refrigerator. If needed, the pen may also be stored at room temperature at 68°F to 77°F (20°C to 25°C) for up to 14 days
 - If refrigerated, leave the pen at room temperature for 30 minutes to allow it to warm up naturally
- 2 PICK a site for injection.
 - You can inject ZYMFENTRA™ either in the front of the thighs or the abdomen
 - Rotate the injection site each time you give an injection

- 3 PLACE the pen on the injection site.
 - Without pinching or stretching the skin, place the pen over the injection site at a 90° angle
- 4 PRESS the pen firmly against the skin.
 - When the injection starts, you will hear the first of 2 click sounds
 - After the second click, continue to hold the pen and count slowly for at least 5 seconds
 - Lift the pen from the injection site

Do not inject ZYMFENTRA without first receiving training from a healthcare professional and reviewing the Instructions for Use.

Important Safety Information

- Risk of cancer (continued):
 - Tell your doctor if you have ever had any type of cancer. Discuss with your doctor any need to adjust medicines you may be taking.

Please see Important Safety Information on pages 14-17.



Scan for step-by-step instructions about how to inject ZYMFENTRA.



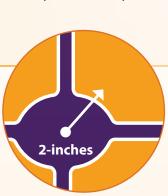
DO NOT shake the pen at any time or use if:

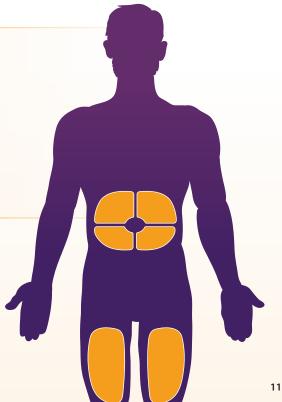
- Cracked or visibly damaged
- The expiration date has passed
- Liquid is discolored or contains particles (medicine should be a clear, colorless to pale brown liquid)

NOTE: Air bubbles are normal.

DO NOT inject into the 2-inch area surrounding your belly button or into skin that is tender, damaged, bruised, or scarred.

2-inches





Ongoing support for patients

At Celltrion, we're here for you throughout your entire treatment journey. From helping you get started on ZYMFENTRA™ and providing injection training, to helping you pay for treatment, we're with you every step of the way.



We have programs in place to help you with:

- Patient benefit verification
- Prior authorization and appeal support
- Co-pay Assistance Program (Celltrion CARES™)
- Financial support for eligible patients in need
- Injection support
- Educational materials
- Sharps containers







Please see Important Safety Information on pages 14-17.



IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ZYMFENTRA?

ZYMFENTRA may cause serious side effects, including risk of infection and cancer.

- Risk of infection: ZYMFENTRA can lower the ability of your immune system to fight infections. Serious infections have happened in patients receiving ZYMFENTRA. These infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body.
 Some patients have died from these infections.
 - Your doctor should test you for TB before starting
 ZYMFENTRA, and should monitor you closely for signs and symptoms of TB during treatment.
 - If you have 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. ZYMFENTRA can make you more likely to get infections or make any infection that you have worse.

Risk of cancer: There have been cases of unusual cancers in children and teenage patients using tumor necrosis factor (TNF) blocker medicines, such as ZYMFENTRA.

- For people receiving TNF blocker medicines, the chances of getting lymphoma or other cancers may increase.
- Some people receiving TNF blockers 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 a TNF blocker and another medicine called azathioprine or 6-mercaptopurine.
- People who have been treated for Crohn's disease or ulcerative colitis for a long time may be more likely to develop lymphoma.
 This is especially true for people with very active disease.
- Some people treated with infliximab products have developed certain kinds of skin cancer. If any changes in the appearance



- of your skin or growths on your skin occur during or after your treatment, tell your doctor.
- Patients with chronic obstructive pulmonary disease (COPD), a specific type of lung disease, may have an increased risk for getting cancer while being treated with ZYMFENTRA.
- Tell your doctor if you have ever had any type of cancer.
 Discuss with your doctor any need to adjust medicines you may be taking.

Do not take ZYMFENTRA if you:

 Have had an allergic reaction to ZYMFENTRA, other infliximab products, any murine proteins, or any of the ingredients in ZYMFENTRA.

Before you receive ZYMFENTRA, tell your doctor about all of your medical conditions, including if you:

- · Have an infection.
- Have other liver problems including liver failure.

- Have heart failure or other heart conditions.
- · Have or have had any type of cancer.
- Have COPD, a specific type of lung disease.
- Have or have had a condition that affects your nervous system such as multiple sclerosis or Guillain-Barré syndrome, or if you experience any numbness or tingling, or if you have had a seizure.
- Have recently received or are scheduled to receive a vaccine.
 Adults should have all their vaccines brought up to date before starting treatment with ZYMFENTRA.
- Are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed.

What should I avoid while taking ZYMFENTRA?

 Do not take ZYMFENTRA together with other medicines called biologics that are used to treat the same conditions as ZYMFENTRA.

IMPORTANT SAFETY INFORMATION continued

What are the possible side effects of ZYMFENTRA?

ZYMFENTRA can cause serious side effects, including:

Serious infections:

- Tell your doctor right away if you have any signs of an infection, including a fever, tiredness (fatigue), a cough, flu-like symptoms, or warm, red, or painful skin.
- Your doctor will examine you for TB and perform a test to see if you have TB.
- If you are a chronic carrier of the hepatitis B virus, the virus can become active while you are being treated with ZYMFENTRA. In some cases, patients have died as a result of hepatitis B virus being reactivated. Your doctor should do a blood test for hepatitis B virus before you start treatment, while you are being treated, and for several months after you finish treatment. Tell your doctor if you have symptoms such as feeling unwell, poor appetite, tiredness (fatigue), fever, skin rash, or joint pain.

Liver injury:

 Some patients receiving infliximab products have developed serious liver problems. Tell your doctor if you have jaundice (skin and eyes turning yellow), dark, brown-colored urine, pain on the right side of your stomach area (right-sided abdominal pain), fever, or extreme tiredness (severe fatigue).

• Heart failure:

- If you have a heart problem called congestive heart failure, your doctor should check you closely while you are receiving ZYMFENTRA. Your congestive heart failure may get worse while you are receiving ZYMFENTRA. Be sure to tell your doctor of any new or worse symptoms including shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Treatment may need to be stopped if you get new or worse congestive heart failure.

Blood problems:

 In some patients receiving infliximab products, the body may not make enough of the blood cells that help fight



infections or help stop bleeding. Tell your doctor if you have a fever that does not go away, bruise or bleed very easily, or look very pale.

Allergic reactions:

- Signs of an allergic reaction can include hives (red, raised, itchy patches of skin), difficulty breathing, chest pain, high or low blood pressure, fever, and chills.
- Tell your doctor right away if you have any of these signs of delayed allergic reaction such as fever, rash, headache, sore throat, muscle or joint pain, swelling of the face and hands, or difficulty swallowing.

Nervous system disorders:

- Tell your doctor if you have changes in your vision, numbness or tingling in any part of your body, seizures, or weakness in your arms or legs.
- Some patients have experienced a stroke within approximately 24 hours of their infusion with infliximab

products. Tell your doctor right away if you have symptoms of a stroke which may include numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion; trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking; dizziness; loss of balance or coordination; or a sudden, severe headache.

• Lupus-like syndrome:

 Your doctor may decide to stop treatment if you develop symptoms such as chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on the cheeks or arms that gets worse in the sun.

The most common side effects include COVID-19, joint pain, respiratory infections such as sinus infections and sore throat, diarrhea, injection site reactions, high blood pressure, headache, urinary tract infections, abdominal pain, dizziness, and abnormal liver enzymes.

Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.



For more questions about **ZYMFENTRA**, talk to your doctor.

www.zymfentra.com

INDICATIONS

ZYMFENTRA is a prescription medicine used as an injection under the skin (subcutaneous injection) by adults for the maintenance treatment of moderately to severely active ulcerative colitis or moderately to severely active Crohn's disease following treatment with an infliximab product given by intravenous infusion (IV).

Please see Important Safety Information on pages 14-17. Please read the Medication Guide found in the pocket for key information on serious side effects.



ZYMFENTRA™ is a trademark of Celltrion, Inc., used under license.
Celltrion Connect® is a registered trademark of Celltrion Holdings, Co., Ltd., used under license.
Celltrion Cares™ is a trademark of Celltrion Holdings, Co., Ltd., used under license.
© Celltrion USA, Inc., 2024 US-ZYM-23-00031 v.2.0 07/24

