

**CROHN'S DISEASE**  
(ages 9 or older)

Patient Support Program

**PfizerFlex**

Experienced, Dedicated Team

**ULCERATIVE COLITIS**  
(ages 6 or older)

Understanding  
your treatment



Your guide to IXIFI<sup>®</sup> and PfizerFlex





# The PfizerFlex Patient Support Program is here to support you

As you (or your child) begin treatment with IXIFI, the PfizerFlex support team is here to offer advice and services to help with your treatment plan. Whether you have Crohn's disease or ulcerative colitis, you can always contact your PfizerFlex Care Coach – a qualified nurse – for any questions or concerns.

This booklet is a great resource for you to learn about your IXIFI treatment and the PfizerFlex program.

Full details about IXIFI can be found in your patient leaflet.

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## Why did your doctor choose IXIFI?

Your doctor has prescribed IXIFI for you, or your child, because of your condition, age, and treatment history:

- **Crohn's disease (CD)** for adults and children aged 9 and older and fistulising CD in adults because the disease is still active, even though you have tried other treatments.
- **Ulcerative colitis (UC)** for adults and children aged 6 and older because the disease is still active, even though you have tried other treatments.

## What type of medicine is IXIFI?

IXIFI is a biosimilar biologic drug, and is part of a class of medications called biologic response modifiers.

## What is a biosimilar?

A biosimilar is a biologic drug product that is authorized based on its likeness to a reference biologic drug product already authorized for sale in Canada.

IXIFI is a biosimilar of the reference biologic drug Remicade®.

# Mechanism of disease

Your immune system works to protect your body from bacteria, viruses, and other foreign agents. In Crohn's disease (CD) or ulcerative colitis (UC), the immune system mistakenly recognizes the body as foreign and attacks healthy body cells.



When you have CD or UC, your immune system overproduces a substance called tumour necrosis factor alpha (or TNF-alpha), which stimulates inflammation.

## How IXIFI works



IXIFI works by binding to and neutralizing TNF-alpha. The active substance in IXIFI, infliximab, is a monoclonal antibody. A monoclonal antibody is a type of protein that recognizes and binds to other unique proteins.

However, IXIFI can also lower the body's ability to fight infections and taking it can make you more prone to getting infections, or make any infection worse.

# How IXIFI is given

IXIFI will be given to you by a healthcare professional as an infusion.

## What is an infusion?

The medicine will be given to you through a needle placed in a vein in your arm. This is called an intravenous (IV) infusion.

During the infusion, you will be monitored for side effects. You must stay for 1 to 2 hours after the infusion so that you can continue to be watched for any reactions to the medicine.



## What is the usual dose?

If you have Crohn's disease or ulcerative colitis, the infusion will take about 2 hours.



### **CROHN'S DISEASE** (for adults and children 9 years or older)

The recommended dose of IXIFI is 5 mg/kg given as an IV infusion.

#### Induction period



#### Maintenance period



for all following infusions

#### **Adults only:**

For people who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg. Your doctor may consider doing a blood test (therapeutic drug monitoring) to determine how much infliximab for injection is in your bloodstream to optimize your dose of IXIFI.

### **ULCERATIVE COLITIS** (for adults and children 6 years or older)

The recommended dose of IXIFI is 5 mg/kg given as an IV infusion.

#### Induction period



#### Maintenance period



for all following infusions

#### **Adults only:**

Your doctor will monitor your response to IXIFI and may change your dose. Your doctor may consider doing a blood test (therapeutic drug monitoring) to determine how much infliximab for injection is in your bloodstream to optimize your dose of IXIFI.

# What should you tell your doctor before starting treatment?

Tell all doctors involved in your care that you take IXIFI.

Before you start taking IXIFI, you should tell your doctor if you have any of the following:

- **Congestive heart failure:** If you have mild heart failure, your heart failure status must be closely monitored by your doctor.
- **Other heart problems:** Some patients have experienced a heart attack (some of which led to death), low blood flow to the heart, or abnormal heart rhythm within 24 hours of beginning their infusion. Symptoms may include chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea, vomiting, fluttering or pounding in your chest, and/or a fast or a slow heartbeat.
- **Immediate allergic reactions:** Some patients developed allergic reactions, including anaphylaxis. Some reactions can happen while you are getting your infusion or shortly afterwards. Some of these reactions have been serious.
- **Delayed allergic reactions:** Some allergic reactions can occur 3 to 12 days after IXIFI retreatment.
- **Nervous system diseases:** If you have multiple sclerosis, neuropathies, Guillain-Barré syndrome, or seizures, or you have been diagnosed with optic neuritis, or if you experience painful and limited eye movements, loss of feeling in the forehead or vision loss (orbital apex syndrome), any numbness, tingling, or visual disturbances.
- **Autoimmune disease:** If you notice symptoms of lupus-like syndrome, such as prolonged chest discomfort or pain, shortness of breath, joint pain, or sun-sensitive rash on the cheeks or arms.
- **Liver injury:** Signs that you could be having liver problems include jaundice (skin and eyes turning yellow), dark brown-coloured urine, right-sided abdominal pain, fever, and severe fatigue (tiredness).



- **Previous phototherapy:** If you have had phototherapy (treatment with ultraviolet light or sunlight along with a medicine to make your skin sensitive to light) for psoriasis.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, including a severely decreased number of white blood cells. Symptoms include persistent fever or infections, bleeding, or bruising.
- **Stroke:** Some patients have experienced a stroke within approximately 24 hours of their infusion. Symptoms 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.
- **Hepatitis B:** Treatment with TNF-blocking agents may result in a reactivation of the hepatitis B virus in people who carry this virus.
- **Vaccination:** Tell your doctor you have received IXIFI if you need to get a vaccination. It's not known if IXIFI can interfere with vaccinations.
- **Therapeutic infectious agents:** If you have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).
- **Pregnancy, breast-feeding and ability to have children:** If you are being treated with IXIFI, you must avoid becoming pregnant by using adequate contraception during your treatment and for 6 months after your last IXIFI injection. If you are breast-feeding, it is important that you tell your baby's doctors and other healthcare professionals about your IXIFI use before your baby is given any vaccine. Live vaccines should not be given to your baby while you are breast-feeding unless your baby's doctor recommends otherwise. Tell your doctor if you think you may be pregnant, are breast-feeding, or planning to conceive a child. If you have a baby and you were using IXIFI during your pregnancy, it is important to tell your baby's doctor and other healthcare professionals about your IXIFI use so they can decide when your baby should receive their vaccinations. It is not known if IXIFI can affect your ability to have children in the future.

Please refer to your patient leaflet for complete safety information.

# Track all of your medications

Tell your doctor about all medicines that you have recently taken or are taking during your treatment with IXIFI. These include any other medicines to treat Crohn’s disease or ulcerative colitis.

Drugs that may interact with IXIFI include: prescription and non-prescription medicines, vitamins, and herbal supplements.

Name	Description (colour, shape, size)	Amount

Use this space to list all the medications you take, including your prescriptions, over-the-counter medicines, herbal products, vitamins, and supplements. Keep this list up to date and share it with your healthcare team at every visit.

How often & when	How to take	What it is for

# Possible side effects

Some patients had side effects that caused them to stop infliximab for injection treatment. The most common reasons were shortness of breath, rash, and headache.

Other common side effects include abdominal pain, back pain, coughing, diarrhea, dizziness, fatigue, itchiness, pain, upper respiratory infections (such as bronchitis, sinusitis, cold, sore throat), upset stomach, and urinary tract infections. IXIFI may have a minor influence on the ability to drive and use machines. Dizziness may occur following administration of IXIFI.

Children and teenagers who took infliximab for injection in studies for ulcerative colitis had similar side effects as adults with ulcerative colitis. The most common side effects observed in children with ulcerative colitis include: cough and cold symptoms including sore throat, stomach pain, fever, headache, and anemia (low red blood cell count). Among patients who took infliximab for injection for ulcerative colitis in clinical studies, more children had infections as compared with adults, including bladder infections, skin infections, and bronchitis.

Some of the side effects of IXIFI can be serious and may require treatment.

## Serious side effects

**Talk to your healthcare professional if you experience any of the following side effects.**

Common:

- **Serious infections:** symptoms of fever, feel very tired, have a cough or develop flu-like symptoms, or develop an abscess.
- **Allergic reactions:** while you are getting your IXIFI infusion or shortly afterwards, hives (red, raised, itchy patches of skin), difficulty breathing, chest pain and high or low blood pressure, or symptoms 3 to 12 days after receiving IXIFI including fever, rash, headache, and muscle or joint pain.

Uncommon:

- **Liver injury:** signs that you could be having a problem include: jaundice (skin and eyes turning yellow), dark brown-coloured urine, right-sided abdominal pain, fever, and severe fatigue (tiredness).
- **Heart failure:** if you have been told that you have a heart problem called congestive heart failure, you will need to be closely monitored by your doctor. New or worse symptoms that are related to your heart condition, including shortness of breath or swelling of your ankles or feet.
- **Blood problems:** fever that doesn't go away, bruising or bleeding very easily, or looking very pale.
- **Nervous system disorders:** signs include changes in your vision (including blindness), seizures, weakness in your arms and/or legs, and numbness or tingling in any part of your body.
- **Malignancy:** if you have had or develop lymphoma or other cancers, including skin cancers, while you are taking IXIFI.
- **Lupus:** symptoms may include chest discomfort or pain that doesn't go away, shortness of breath, joint pain, or a rash on the cheeks or arms that gets worse in the sun.

Rare:

- **Skin problems:** skin rashes including redness, itching, skin peeling and blistering; small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis); itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes (lichenoid reactions).
- **Lung problems:** symptoms of new or worsening shortness of breath.

**These are not all the possible side effects you may have when taking IXIFI. If you experience any side effects not listed here, tell your healthcare professional.**

Please refer to your patient leaflet for complete safety information.

# Exploring your PfizerFlex Program

## Focused on you

Designed with patients like you in mind, the PfizerFlex Program gives you access to important treatment information and assistance to support you in getting the most out of your IXIFI treatment plan.

### Support for every step of your treatment plan

**Live support** from our dedicated team and your Care Coach (nurse) about the program or your treatment



**Reimbursement expertise** to help you find and secure coverage for your treatment



**Experienced team members** to help you access your medication as quickly as possible



**Access to a reliable infusion clinic network** staffed with qualified healthcare professionals



**Practical tools** to help you navigate your treatment plan







To access [ixifi.ca](https://ixifi.ca), use the DIN 02523191

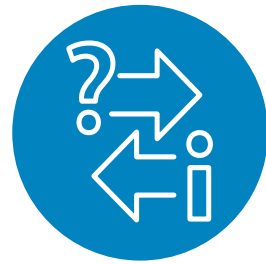


## Coaches who care

**Your dedicated PfizerFlex Care Coach** is a nurse and an important member of your support team. The PfizerFlex program has a lot of personalized support and advice to offer, and your Care Coach will be the one who guides you through this process.

Your Care Coach will:

- Assist you in exploring your financial assistance options
- Help you begin your treatment with IXIFI
- Help empower you to understand and manage elements of your treatment plan



Your Care Coach is a nurse who will help you organize your infusion time and place. You can also use the **Clinic Locator** section of the [ixifi.ca](https://ixifi.ca) website to help you find a clinic most convenient for you. The PfizerFlex program clinics are staffed by qualified healthcare professionals specially trained in the administration of IXIFI infusions and are available across Canada, for both first-time users and people switching treatment.

### Meeting your Care Coach

Within one business day of enrolment, you'll receive a phone call from a Care Coach — a registered nurse — to help you discover how the program can best support you.

**For more information or to reach your Care Coach, call 1-855-935-FLEX (3539).**

# Preparing for your appointment

## Taking advantage of your support teams

It is essential in any treatment to follow your prescription and to let your healthcare professional know what other medications you are taking before starting a new treatment.



Your treatment support team can help you manage your treatment day to day, and discuss and help you with any of your concerns regarding your condition and your treatment.

If you are feeling anxious or uncertain, talk to your doctor or Care Coach for support. They will also be able to provide you with details for where to access infusion clinic services near you. It can also be helpful to discuss the possible treatment outcomes you wish to achieve, which ones are most important to you and why.



Bring this list to your next appointment with your healthcare professional.

1. Use the table below to list and prioritize your desired possible treatment outcomes.

Priority	Outcomes
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

2. Consider your top priority (priority 1) from the list and answer the following questions:

a. Why is this important to me?

b. How will this benefit me?

c. How would I feel if I couldn't achieve this outcome?

## Before your infusion

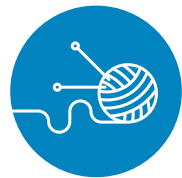
Before leaving the house for the clinic, it might be helpful to remember to:

- Wear comfortable loose-fitting clothes
- Bring layers (like a sweater)
- Be mindful of others and not wear any fragrance or perfume
- Bring a neck pillow for comfort



## During your infusion

The infusion can take about 2 hours to complete, and you will not be able to stand up and walk around. Consider reading a book or filling out a crossword puzzle, knitting or listening to music with your headphones on, or even chatting with your neighbour.



During the infusion, you will be monitored for side effects.

## After your infusion

You must stay for 1 to 2 hours after the infusion so that you can continue to be watched for any reactions to the medicine.

Ask any questions to the staff you may not have thought of before and make a note of when your next appointment is scheduled in order to keep track.



# Basic facts about Crohn's disease

## What is Crohn's disease (CD)?

CD is a chronic condition where part of the lining of the digestive system becomes inflamed, most commonly the lower part of the small intestine and the upper colon.

CD is slightly more common in women than in men. It can start at any age, but is most likely to develop in people between the ages of 15 and 35.

## What are the symptoms?

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### **Common symptoms:**

- Diarrhea
  - Fever
  - Sores in the mouth and around the anus
  - Abdominal pain and cramping
  - Anemia
  - Tiredness
  - Loss of appetite
  - Weight loss
- 

People with CD usually experience periods of active symptoms (called flares) and other times there may be no symptoms (called remission).

## What causes it?

It is not known what causes CD, but it is believed to involve your genes (genes contain the blueprint for each individual's specific traits), immune system, and environmental factors.

## How is the immune system involved?

The immune system is designed to attack foreign substances, such as viruses, bacteria, or other pathogens.

In CD, it is believed that an abnormal immune response causes the immune system to mistake food, harmless bacteria, and other materials in the intestine as invaders. This causes white blood cells to flood the area, which leads to inflammation.

## Does family history matter?

Genetic factors are likely to be involved because having family members with CD increases your risk of developing the condition.

## Are there any environmental factors?

Environmental factors, including deficiency in vitamin D from not getting enough sunlight, use of certain other drugs, smoking, and air pollution can increase the likelihood of developing CD. Processed foods, including foods high in fat and additives, may also be contributing factors.

The information provided here is on the condition and may not reflect benefits of the product.

# Basic facts about ulcerative colitis

## What is ulcerative colitis (UC)?

UC is a long-term condition causing inflammation and ulcers in the lining of the large intestine (colon), most commonly the last part of the colon and the rectum.

UC can start at any age, but is most likely to develop in people between the ages of 15 and 45.

## What are the symptoms?

People with UC usually experience periods of active symptoms (called flares) and other times there may be no symptoms (called remission).

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### **Common symptoms:**

- Bloody diarrhea
  - Mild fever
  - Abdominal pain and cramping
  - Anemia
  - Fatigue
  - Loss of appetite
  - Weight loss
-



## What causes it?

It is not known what causes UC, but it is believed to involve your genes (genes contain the blueprint for each individual's specific traits), immune system, and environmental factors.

## How is the immune system involved?

The immune system is designed to attack foreign substances, such as viruses, bacteria, or other pathogens.

In UC, while the immune system tries to fight off invading foreign substances, an abnormal immune response also causes the immune system to mistake food, harmless bacteria, and other materials in the intestine as invaders. This causes white blood cells to flood the area, which leads to inflammation.

## Does family history matter?

Genetic factors are likely to be involved because having family members with UC increases your risk of developing the condition.

## Are there any environmental factors?

Environmental factors, including use of certain other drugs, and lack of vitamin D from reduced sunlight can all increase the likelihood of developing UC. Processed foods, including foods high in fat and additives, may also be contributing factors.

The information provided here is on the condition and may not reflect benefits of the product.

# What can your friends and family do to help?

## Your support system

Sharing what you are going through with family and friends can help you feel understood and supported.

People often say that it is helpful to go to their medical appointments with someone they trust. That person can take notes, ask questions you may forget, and support you in making decisions with your physician.

**Some people find that getting in touch with others going through the same experience can be helpful.**



# How can you help yourself with lifestyle changes?

## Live a healthy lifestyle

Changes in your diet, exercising regularly, getting enough rest, and minimizing stress may help control your symptoms of Crohn's disease and ulcerative colitis.

### Dietary suggestions

Although no diet has been shown to cause Crohn's disease and ulcerative colitis, certain foods and beverages can aggravate your signs and symptoms, especially during a flare-up.



Limit dairy products



Monounsaturated fats may be good options to try



Limit fibre during flare-ups



Avoid spicy foods, alcohol, and caffeine



Eat small meals



Drink plenty of fluids



Consult a dietitian for more information

### Manage your stress



Mild exercise can help reduce stress and anxious feelings, and normalize bowel function



Regular relaxation and breathing exercises can help you cope with stress

# Additional resources

In addition to the various resources offered by the IXIFI website **ixifi.ca**, like the Clinic Locator, you can also find links to other certified websites that may be useful. Please note that this is not a complete list of the available resources you may find.

## These websites include:

- Crohn's and Colitis Canada  
[www.crohnsandcolitis.ca](http://www.crohnsandcolitis.ca)
- Canadian Digestive Health Foundation  
[www.cdhf.ca](http://www.cdhf.ca)
- Crohn's and Colitis Foundation  
[www.crohnscolitisfoundation.org](http://www.crohnscolitisfoundation.org)
- American Society of Colon and Rectal Surgeons  
[www.fascrs.org](http://www.fascrs.org)
- Crohn's and Colitis  
[www.crohnsandcolitis.com](http://www.crohnsandcolitis.com)

## Apps

Apps can modernize the way you track your treatment plan. Some of these apps are free and available on Google Play or the App Store.

Search for these apps using your phone's app store:

- MyGut™: Crohn's & Colitis Canada
- Gali Health
- Colitis Tracker
- myColitis
- MyGiHealth GI Symptom Tracker

# Additional lifestyle support



As an IXIFI patient, you may receive access to the LyfeMD App, a nutrition and lifestyle app available to help you manage your CD or UC through healthy changes. Contact your Care Coach for more information.

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**Call your Care Coach today! 1-855-935-FLEX (3539)**

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use the DIN 02523191**

# Glossary

**Autoimmune disease** – a type of disease where the the body's immune system attacks and destroys healthy body tissues.

**Bowel** – another name for the intestine. The small and large bowels are the small and large intestines, respectively.

**Chronic illness** – an illness that lasts a long time. Usually, it develops slowly and is rarely cured completely.

**Colon** – the large bowel (large intestine).

**Crohn's disease (CD)** – a chronic disorder that causes inflammation of any area of the gastrointestinal (GI) tract from the mouth to the anus, although it most commonly affects the small intestine and colon.

**Gastroenterologist** – a physician who specializes in the diagnosis and treatment of diseases of the gastrointestinal tract, such as the stomach, intestines, colon, and rectum.

**Gastrointestinal tract** – collectively refers to the mouth, esophagus, stomach, small and large intestines, and anus.

**Immune system** – the immune system is made up of cells, organs, and tissues that work together to keep our bodies healthy. The immune system attacks and removes pathogens to prevent us from getting ill.

**Inflammation** – an immune response with signs such as redness, heat, pain, and swelling.

**Intestine** – the intestine is made up of the small and large intestines. The small intestine digests food and absorbs nutrients. The large intestine, also called the colon, is wider in diameter, and removes water and salt from feces.

**Rectum** – the lowest portion of the large intestine that connects to the anus.

**Ulcerative colitis (UC)** – a chronic disease of the colon characterized by inflammation and ulcers on the lining of the colon. Affected organs can include the rectum and the entire colon.

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## 1-855-935-FLEX (3539)

For more information or to contact your Care Coach  
(Monday – Friday, 8:00 AM – 8:00 PM EST)

You have access to a network of clinics located across Canada and staffed by qualified healthcare professionals specially trained in the administration of IXIFI.

We're here to provide you with treatment support from the first prescription and throughout your treatment journey.

**The PfizerFlex Patient Support Program will work with you to find the most convenient location for your treatment.**

Visit [ixifi.ca](https://ixifi.ca)

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Patient Support Program

**PfizerFlex**

Experienced, Dedicated Team

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