## Important

- **If you have any serious side effects or side effects that do not go away, tell your IBD health care provider right away so they can make changes to your medication.** Side effects can usually be controlled with other medications, but you may need to lower your IL-23 inhibitor dose (amount) or stop taking it.
- Talking with your IBD health care provider when you see any changes in your side effects will help you pick the treatment that is right for you.

This pamphlet is for educational purposes only. It is not intended to replace the advice or professional judgment of a health care provider. The information may not apply to all situations. If you have any questions, please ask your health care provider.

Connect with a registered nurse in Nova Scotia any time:
Call 811 or visit: https://811.novascotia.ca

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Patient & Family Guide
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# IL-23 Inhibitor Therapy for Inflammatory Bowel Disease (IBD)

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# IL-23 Inhibitor Therapy for IBD

Your inflammatory bowel disease (IBD) health care provider feels that treatment with an IL-23 inhibitor may help you manage your IBD (like Crohn's disease, ulcerative colitis).

This pamphlet can help you choose whether to use this treatment. It does not replace your IBD health care provider or pharmacist's instructions or information.

## What is IBD?

- In IBD, your immune system cannot tell the difference between foreign (from outside your body) substances and your body's own tissues. This can cause:
  - Bowel inflammation (swelling)
  - Bowel ulcers (sores)
  - Diarrhea (loose, watery poop)
  - Pain
- IBD is usually treated with medications that:
  - Lower inflammation
  - Suppress (lower) the immune system



- If you get an infection while taking an IL-23 inhibitor, tell your IBD health care provider. They will tell you if you should delay your treatment and when you should start it again. If the infection becomes serious, your treatment may be stopped.

**Call 911 or go to the nearest Emergency Department right away if you suddenly have any of these symptoms after injecting an IL-23 inhibitor:**

- Shortness of breath or trouble breathing
- Chest pain
- Swelling in your face, throat, legs, or feet
- Skin rash
- Itchy skin
- Anaphylaxis (a life-threatening allergic reaction where you stop breathing)

  - Liver problems (if you are taking risankizumab). **Tell your health care provider if you have any of these side effects:**
    - Tiredness
    - Loss of appetite (not feeling hungry)
    - Pain on the right side of your stomach (belly)
    - Dark urine (pee)
    - Jaundice (yellowing of the skin and eyes)
- Your IBD health care provider will ask you to have blood tests every 3 months to check your liver.
- **Tell your health care provider if you have any of these signs of an infection:**
  - Fever (temperature above 38 °C or 100.4 °F)
  - Chills
  - Cough
  - Hoarse (sore) throat
  - Pain in your lower back or side
  - Pain or trouble when urinating (peeing)
  - Headache
- **If you think you have an infection, visit your primary health care provider (family doctor or nurse practitioner) or go to a walk-in clinic. It is important to tell them that you are taking an IL-23 inhibitor.**



## What is an IL-23 inhibitor?

- IL-23 inhibitors are medications that are often used to treat IBD. They block the protein called **interleukin-23** (IL-23) that causes chronic (ongoing) inflammation in IBD.
- Medications include:
  - Risankizumab (Brand name: Skyrizi®)
  - Guselkumab (Brand name: Tremfya®)
  - Mirikizumab (Brand name: Omvoh®)
- IL-23 inhibitors are **biologic medications**. A biologic medication is a special medication that treats inflammation.

## How do these medications work?

- Your immune system uses white blood cells to defend itself when you are sick and to attack germs.
- IBD is a disease that can cause your immune system to be too active. If you have too many white blood cells or too much IL-23 protein, it can make the lining of your intestines (bowel) swell. Inflammation can damage your body tissues and organs.
- IL-23 inhibitors block IL-23 protein. This helps to lower swelling, pain, and many other IBD symptoms.

## How long will I need to take this medication?

- IL-23 inhibitors can take up to 4 months to work well. Your IBD health care provider will check how you are responding to the medication and decide if it is right for you.
- You can check if the medication is working by keeping a record of your IBD symptoms. Your IBD health care provider can also do the following tests:
  - Stool (poop) sample
  - Colonoscopy (scope of the bowel)
- Your IBD health care provider may want you to stay on an IL-23 inhibitor long term (years) to treat your IBD if:
  - The medication is helping your IBD symptoms
  - You do not have any major side effects

## How much do IL-23 inhibitors cost?

- IL-23 inhibitors can cost thousands of dollars a month.
- A Patient Support Program is available to help with the cost of your IL-23 inhibitor. They will work with your insurance company or Nova Scotia Pharmacare. Any part of the cost that is not covered by your insurance or Pharmacare may be paid for by the Patient Support Program.



## What are the possible side effects of IL-23 inhibitors?

- Like any medication, IL-23 inhibitors have possible side effects. These include:
  - Redness at the injection site (where the needle is inserted)
  - Tiredness
  - Headache
  - Itchy skin
  - Infection in your nose, throat, or windpipe (tube that connects your throat and lungs)
  - Fungal skin infection
  - Vaginal yeast infection

## Higher risk of infection

- IL-23 inhibitors work by lowering the immune responses that cause your IBD symptoms, but they also lower other immune responses. This means you may have a higher risk of:
  - Infection
  - A serious allergic reaction

## While you are taking an IL-23 inhibitor

- **Do not get any live vaccines (vaccines that have a weakened form of a virus in them, like MMR).** You are at a higher risk of infection from the virus.
- If you are due for vaccines or plan to be vaccinated, tell your IBD health care provider. It is safe to get the yearly influenza vaccine (flu shot) and COVID vaccines while taking an IL-23 inhibitor.
- **If you have other health problems, they may get worse while taking an IL-23 inhibitor. Tell your IBD health care provider about any other health problems you have, like:**
  - Allergies to certain medications
  - Chronic or recurrent (keep coming back) infections
  - Blood conditions
  - History of or exposure to TB
  - Chronic obstructive pulmonary disease (COPD)
  - Active cancer or a history of cancer
  - Congestive heart failure (CHF)



- A nurse coordinator for the Patient Support Program will stay in contact with you and your IBD health care providers. They will help you with any forms that may be needed to cover the cost of this medication.

## How are IL-23 inhibitors given?

- An IL-23 inhibitor can be:
  - Given by an intravenous (I.V.) infusion (injected into a vein using a needle)

  **or**
  - Self-injected
- **It cannot be taken by mouth.**
- At the start of your treatment (induction), your IBD provider may prescribe this medication as an infusion.
- During an infusion, the medication is given through a small, flexible tube put into a vein in your arm.
- The infusions will take place at a private infusion clinic in your area.
- Each infusion will take about 1 hour (60 minutes).
- You will get 1 infusion every 30 days (1 month) for 3 months.
  - One (1) month after your 3rd infusion, you will come to the clinic and learn how to do the injections yourself.

- The nurse at the infusion clinic will show you how to use:
  - An **on-body injector** for risankizumab
  - An **injector pen** for guselkumab and mirikizumab
- They will help you inject your first dose and make sure you know how to give yourself injections at home.
- When you and the nurse feel that you are comfortable doing the injections yourself, you will do them once every 4 to 8 weeks (1 to 2 months). This will help to control your symptoms.
- If you are **not** comfortable doing self-injections, you can come to the infusion clinic for support or to have a nurse give you your injection.

**If you are starting guselkumab:**

- Your IBD provider may prescribe self-injections instead of infusions to start your treatment.
  - If self-injections are prescribed, you can inject the first 3 treatments yourself, once a month. A nurse will teach you how to give yourself the injections.

**Do not try to inject this medication on your own until you fully understand how.**



## Before you start taking an IL-23 inhibitor

- Before taking an IL-23 inhibitor, there are things you can do to lower your risks and help the treatment work better.
- You will have tests to check for active infections, like:
  - Blood tests
  - A tuberculosis (TB) skin or blood test
  - A chest X-ray
- Your IBD health care provider may want you to update your vaccines for:
  - Hepatitis
  - Pneumonia (lung infection)
  - Shingles
  - Tetanus
- **Do not start taking any new medications.** Medication interactions (how they affect each other) may raise your risk of serious side effects. **Ask your IBD health care provider or pharmacist about possible complications before starting a new medication** (including prescription and over-the-counter products, herbal products, vitamins, and supplements).
- Tell your health care provider if you are pregnant, plan to get pregnant, or do get pregnant. It is safe to take an IL-23 inhibitor during pregnancy.
- It is safe to breastfeed or chestfeed while taking an IL-23 inhibitor.