

Upadacitinib Therapy for Inflammatory Bowel Disease (IBD)

- **It is very important that your IBD health care provider checks your progress at regular visits to make sure this medication is working the right way.** You will also need regular blood tests. Talk to your IBD health care provider about when they will follow up with you by phone or in-person.

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.

Find all patient education resources here:
www.nshealth.ca/patient-education-resources

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

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- **If you think you have an infection, visit your primary health care provider or go to a walk-in clinic. It is important to tell them that you are taking upadacitinib.**
- If you get an infection while taking upadacitinib, tell your IBD health care provider. They will tell you if you should delay your upadacitinib treatment and when you should start it again. If the infection becomes serious, your treatment may be stopped.

What should I do if I have side effects?

- If you have any serious side effects, or you have side effects that do not go away, tell your IBD health care provider right away. You may have to lower your dose or stop taking upadacitinib. They will make changes to your medication, if needed.
- There are other medications that can help you manage the symptoms of these side effects.
- **It is important to talk with your IBD health care provider as soon as you have any changes in your side effects.** This will help you and your IBD health care provider pick the treatment that is best for you.

Upadacitinib Therapy for IBD

Your inflammatory bowel disease (IBD) health care provider thinks that treatment with upadacitinib may help you manage your IBD. This pamphlet has basic information about upadacitinib. It 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

Call 911 or go to the nearest Emergency Department right away if you suddenly have any of these symptoms:

- › Trouble breathing
- › Chest pain
- › Swelling in your face, throat, legs, or feet
- › Anaphylaxis (a life-threatening allergic reaction where you stop breathing)

Higher risk of infection

- Upadacitinib works by lowering the immune responses that cause your IBD symptoms, but it also lowers other immune responses. This means you may have a higher risk of infection.

There is a very small chance of getting an infection that could cause death.

- Some people on upadacitinib have had infections. These range from a cold to more serious infections which could cause death, like:
 - › Pneumonia
 - › Tuberculosis (TB)
 - › Other bacterial, fungal, and viral infections

What is upadacitinib?

- Upadacitinib is a **Janus kinase (JAK) inhibitor**. JAK is an enzyme in your body which helps to turn on your immune system when you need it.
- When JAK is too active, it can cause inflammation that could lead to swelling, redness, and/or pain in the bowel.
- Upadacitinib lowers JAK's activity.

How long will I need to take upadacitinib?

- Your symptoms may start to improve within days or weeks, or it may take longer (a few months). After your first few months of taking upadacitinib, your IBD health care provider will check how you are responding to it 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)

What are the possible side effects of upadacitinib?

- Like any medication, upadacitinib has possible side effects. These include:
 - › Throat and nose infections
 - › Weight gain
 - › Skin rash
 - › Cough
 - › Shingles (this can be lowered with a vaccine before you start taking upadacitinib)
 - › Headache
 - › Higher cholesterol
 - › Nausea (upset stomach)
 - › Cold sores
 - › Back pain
 - › Acne (pimples)
- **There is a very small chance of more serious side effects, like:**
 - › Serious infection
 - › Blood clots
 - › Skin cancer
 - › Heart problems
 - › Liver problems

- **Tell your IBD health care provider if you use tobacco.**
- **Do not get any live vaccines (vaccines that have a weakened form of a virus in them, like MMR) while taking upadacitinib.** 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 upadacitinib.
- **Do not start taking any new medications.** Medication interactions (how they affect each other) may increase your risk of serious side effects. **Ask your IBD health care provider or pharmacist about possible complications before starting a new medication.**
- Have regular blood tests and regular check-ups with your primary health care provider (family doctor or nurse practitioner).
- **It is important to tell your IBD health care provider if you are, or are trying to get, pregnant.** It is not yet known if it is safe to take upadacitinib while you are pregnant.
- **It is important to tell your IBD health care provider if you are breastfeeding or chest feeding.** It is not yet known if it is safe to breastfeed or chest feed your baby while taking upadacitinib.

- Your IBD health care provider may want you to stay on upadacitinib long-term (years) to treat your IBD if:
 - › The medication is helping your IBD symptoms
 - › You are not having any major side effects

How much does upadacitinib cost?

- Upadacitinib can cost thousands of dollars a month.
- A Patient Support Program is available to help with the cost of this medication. 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.
- 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 paperwork that may be needed to cover the cost of this medication.

How do I take upadacitinib?

- Upadacitinib comes as a tablet. It is taken orally (by mouth) once a day.
- Swallow the tablets whole with water at about the same time each day. **Do not split, crush, or chew the tablets.**
- You can take it with or without food.
- **Do not** change your dose (amount) unless your IBD health care provider tells you to.
- **For the first 8 to 12 weeks** (2 to 3 months): The recommended oral dose is one 45 mg tablet once a day.
- **For long-term treatment** (after 8 to 12 weeks): The recommended oral dose is one 15 mg or one 30 mg tablet once a day. Your IBD health care provider will prescribe the right dose for you and tell you how much to take.
- **It is very important to take this medication exactly as your IBD health care provider tells you. Do not** stop taking it before talking to your IBD health care provider.
- **If you miss a dose:**
 - › Take it as soon as you remember.
 - › **Do not take more than 1 tablet a day.**

Before you start taking upadacitinib

- Before taking upadacitinib, there are things you can do to lower your risks (see page 10) 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:
 - › Tetanus
 - › Pneumonia (lung infection)
 - › Shingles
 - › Hepatitis
- **If you have other health problems, they may get worse while taking upadacitinib. Be sure to tell your IBD health care provider about any other health problems you have, like:**
 - › Chronic or recurrent (keep coming back) infections
 - › History of or exposure to TB
 - › Active cancer or a history of cancer
 - › Heart problems (like a heart attack) or risk factors for heart problems (like high blood pressure or high cholesterol)
 - › History of blood clots
 - › Kidney problems
 - › Shingles