

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrRINVOQ®

upadacitinib extended-release tablets

Read this carefully before you start taking **RINVOQ** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **RINVOQ**.

Serious Warnings and Precautions

Serious Infections

- You should not take RINVOQ if you have any kind of infection.
- RINVOQ is a medicine that affects your immune system. It can lower the ability of your body to fight infections. Examples of these types of infection are tuberculosis, shingles (herpes zoster) or cryptococcosis, or infections caused by other bacteria, fungi or viruses that can spread throughout your body.
- In some cases, these infections may lead to hospitalization or death.
- Most patients taking RINVOQ who developed these infections were also taking other medicines, such as methotrexate or corticosteroids. These medicines may have made it harder to fight infections.
- Contact your healthcare professional if you have:
 - fever, sweating, chills,
 - muscle aches,
 - cough,
 - shortness of breath,
 - coughing up blood,
 - weight loss,
 - warm, red, or painful skin or sores on your body,
 - diarrhea or stomach pain,
 - burning when you urinate or urinating more often than normal,
 - feeling very tired.

These may be signs that you have an infection.

- Your healthcare professional will monitor you for the signs and symptoms of infection during and after your treatment with RINVOQ.

Cancers

Lymphoma and other cancers have been reported in patients treated with RINVOQ.

Blood clots

- Deep vein thrombosis (blood clots in the veins of your legs), pulmonary embolism (blood clots in the lungs) or arterial thrombosis (blood clot in an artery) have occurred in patients taking RINVOQ and other similar medications. These blood clots can be life-threatening and cause death.
- If you develop any signs or symptoms of a blood clot in your leg (such as swelling, pain or tenderness in the leg) or in your lung (such as sudden unexplained chest pain or shortness of breath) stop RINVOQ and seek immediate medical help.

What is RINVOQ used for?

RINVOQ is used to treat adults with rheumatoid arthritis when treatment with methotrexate has not worked well or was not tolerated well. RINVOQ may be taken alone or in combination with other medicines.

RINVOQ is not recommended for use in children and adolescents under 18 years of age.

How does RINVOQ work?

RINVOQ is a 'Janus kinase' (JAK) inhibitor. JAK is an enzyme in your body, which normally helps to turn on your immune system when you need it. The immune system then causes swelling and tenderness, which is called inflammation. In people with rheumatoid arthritis who experience inflammation and pain in their joints, RINVOQ will attach to the JAK enzyme to lower its activity. This can improve the signs and symptoms of rheumatoid arthritis and help to slow damage to your bone and joints.

What are the ingredients in RINVOQ?

Medicinal ingredient: upadacitinib (as upadacitinib hemihydrate)

Non-medicinal ingredients: colloidal silicon dioxide, ferrousferrous oxide (E172), hypromellose, iron oxide red (E172), magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, tartaric acid, and titanium dioxide. The tablets are gluten-free.

RINVOQ comes in the following dosage forms:

Extended-release tablets: 15 mg upadacitinib

Do not use RINVOQ if:

- you are allergic to upadacitinib or any of the other ingredients in RINVOQ.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RINVOQ. Talk about any health conditions or problems you may have, including if you:

- have or have had tuberculosis (TB). You may need tests to check for TB before you are given RINVOQ. Tell your healthcare professional if you get a persistent cough, fever, night sweats and weight loss during RINVOQ treatment. These can be signs of TB.
- have had a herpes infection (shingles). This is because RINVOQ may allow it to come back. Tell your healthcare professional if you get a painful skin rash with blisters during RINVOQ treatment. These can be signs of shingles.
- have or have had liver problems or hepatitis B or C.
- have recently had or plan to have a vaccination (immunization). You should not be given certain types of vaccines while using RINVOQ.
- have or have had cancer. Your healthcare professional will decide if you can still be given RINVOQ.
- have high cholesterol.
- have or have had diverticulitis (inflammation in parts of your large intestine), or gastrointestinal perforation (tears in your stomach or intestine). Some people taking RINVOQ can get tears in their stomach or intestines. Patients taking medications called non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids or those who have diverticulitis are more likely to have a gastrointestinal perforation.
- have low blood cell counts. Treatment with RINVOQ can be associated with anemia (low red blood cells), neutropenia or lymphopenia (low white blood cells).
- have muscle pain and / or muscle weakness.

Other warnings you should know about:

Cancer

Lymphoma and other cancers, including skin cancer, have been reported in patients treated with RINVOQ. Your healthcare professional will monitor you for the signs of skin cancer.

Blood tests

You may need blood tests before you start RINVOQ. These tests may be repeated while you are taking RINVOQ. These will help your healthcare professional to know how RINVOQ is affecting your blood and how well your liver is working.

Pregnancy and breastfeeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before taking this medicine. You should not use RINVOQ if you are pregnant.
- Avoid becoming pregnant while taking RINVOQ. It may harm your unborn baby. Use effective birth control while you are taking RINVOQ, and for at least 4 weeks after your last dose of RINVOQ. If you become pregnant during this time, tell your healthcare professional right away.
- You should not use RINVOQ if you are breastfeeding. It is not known if RINVOQ passes into breast milk. You and your healthcare professional should decide if you will take RINVOQ or breastfeed. Talk to your healthcare professional about the best way to feed your baby while you are being treated with RINVOQ.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with RINVOQ:

- medications for fungal infections (such as ketoconazole, itraconazole, posaconazole or voriconazole).
- a medication to treat bacterial infections called clarithromycin.
- a medication to treat bacterial infections like TB called rifampicin.
- a medication to prevent seizures called phenytoin.
- medications that affect your immune system (such as azathioprine, cyclosporin, and tacrolimus).
- an herbal remedy used mainly for depression called St-John's Wort (*hypericum perforatum*).
- products or juices containing grapefruit. Avoid eating or drinking any products or juices containing grapefruit while taking RINVOQ.

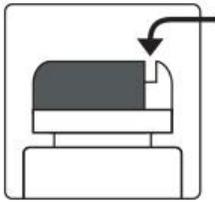
These products may affect the amount of RINVOQ in your blood.

How to take RINVOQ:

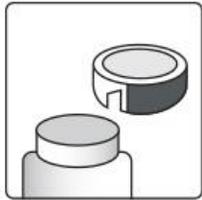
- Take exactly as your healthcare provider tells you.
- Take once per day with or without food.
- Swallow tablets whole with water at about the same time each day.
- Do NOT split, crush or chew the tablets.
- Do not change your dose.
- Do not stop taking RINVOQ without first talking with your healthcare provider.

How to open the bottle and puncture the foil:

RINVOQ tablets will be given to you in bottles. Each bottle is sealed with foil and then closed with a cap. The cap has a cutting tool that can be used to help you puncture the foil seal.

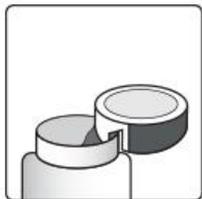


1. The cap of the RINVOQ bottle has a foil cutting tool.

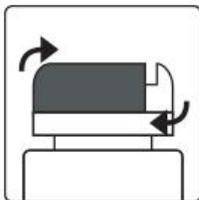


2a. To remove the cap from the bottle, push down and (at the same time) turn the cap counterclockwise.

2b. Turn the cap over. Place the cutting tool near the edge of the foil seal.



3. Push down to make a hole in the foil. Move the cutting tool around the edge of the foil. This will cut the foil all the way around.



4. When you have taken your tablet, put the cap back on and close the bottle.

Usual dose: One (15 mg) tablet per day

Your healthcare professional may interrupt your treatment with RINVOQ if you have certain side effects.

Overdose:

If you think you have taken too much RINVOQ, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose of RINVOQ, take your dose as soon as you remember. However, do not take more than 1 tablet per day.

What are possible side effects from using RINVOQ?

These are not all the possible side effects you may feel when taking RINVOQ. If you experience any side effects not listed here, contact your healthcare professional.

- throat and nose infections
- cough
- headache
- nausea

- cold sores
- back pain

RINVOQ can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Pneumonia (lung infection): Coughing, fever, fatigue		✓	
UNCOMMON			
Bronchitis (inflammation in the lung): persistent cough with or without mucus, fatigue, shortness of breath		✓	
Fever		✓	
Herpes Zoster (shingles): painful skin rash with blisters and fever			✓
Pulmonary embolism (blood clot in the lung): sharp chest pain, coughing up blood, sudden shortness of breath			✓
Deep vein thrombosis (blood clot in the deep veins of the leg or arm): swelling, pain, arm or leg may be warm to the touch and may appear red			✓
Anemia (low red blood cells): shortness of breath, feeling very tired, pale skin, fast heartbeat, loss of energy, weakness		✓	
Urinary tract infection: difficulty or increased need to urinate, pain or burning sensation when peeing, pain in the pelvis or middle of the back, urine that is cloudy or bloody		✓	
Cellulitis (skin infection): redness, swelling, painful skin		✓	
New cancers (skin and other organs)		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, itching			✓
RARE			
Oral candidiasis (thrush in the mouth): thick white patches in the mouth, tongue or on the throat, sore throat		✓	
Gastrointestinal perforation (tear in the stomach or intestinal wall): abdominal pain, feeling sick, vomiting, constipation, fever			✓
Arterial thrombosis (blood clot in an artery): chest pain, shortness of breath, dizziness, face drooping on one side, weakness in one arm, slurred speech, limbs may become painful, skin on limb may be pale or blue in colour and cold			✓
Neutropenia, leukopenia or lymphocytopenia (low white blood cells): fever or infection, fatigue, aches and pains, flu-like symptoms, swollen lymph nodes, painful joints		✓	
Increased Creatinine Phosphokinase (CPK; CPK is an enzyme found in the blood when there is muscle damage): muscle aches, pain or stiffness; muscle weakness	✓		
Hypercholesterolemia (high cholesterol)		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2 and 25°C in the original bottle to protect from moisture.
Keep out of reach and sight of children.

If you want more information about RINVOQ:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (www.canada.ca/en/health-canada), the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

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