

Rinvoq®

upadacitinib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Rinvoq. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Rinvoq against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Rinvoq is used for

Rinvoq contains the active ingredient upadacitinib. It is used to treat:

- Moderately to severely active rheumatoid arthritis in adults. Rheumatoid arthritis is a disease that causes inflamed joints.
- Moderate to severe atopic dermatitis, also known as atopic eczema, in adults and adolescents 12 years and older. Rinvoq may be used with eczema medicines that you apply to the skin or it may be used on its own.
- Active psoriatic arthritis in adults. Psoriatic arthritis is a disease that causes inflamed joints and psoriasis.
- Active non-radiographic axial spondyloarthritis in adults. Non-radiographic axial spondyloarthritis

is a disease that primarily causes inflammation in the spine.

- Active ankylosing spondylitis in adults. Ankylosing spondylitis is a disease that primarily causes inflammation in the spine.
- Moderately to severely active ulcerative colitis in adults when conventional therapy or a biologic medicine like a medicine called a tumour necrosis factor (TNF) did not work well or cannot be tolerated.
- Moderately to severely active Crohn's disease in adults. Crohn's disease is an inflammatory disease of the bowel.

A family of enzymes known as Janus Kinase (JAK) creates signals in the body's immune system that result in inflammation. Rinvoq belongs to a group of medicines called JAK inhibitors. It works by reducing the activity of Janus Kinase enzyme in the body. In doing so, Rinvoq helps to reduce inflammation and treat the following diseases:

Rheumatoid Arthritis

In rheumatoid arthritis, upadacitinib helps to reduce pain and stiffness and swelling in your joints, and tiredness. It helps to slow damage to the bone and cartilage in your joints. These effects can help you to do normal daily activities and improve your health-related quality of life.

Atopic Dermatitis

Using Rinvoq can improve the condition of your skin and reduce itching and flares. Rinvoq has also been shown to improve symptoms of pain, anxiety, and depression associated with atopic dermatitis. In

addition, Rinvoq helps reduce the impact of atopic dermatitis on the overall quality of your life including your sleep disruption, daily activities, emotional state (sadness, embarrassment, and self-consciousness).

Psoriatic arthritis

Rinvoq helps to reduce pain, stiffness, and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash and tiredness. It helps to slow damage to the bone and cartilage in your joints. These effects can help you to do normal daily activities and so improve your health-related quality of life.

Non-radiographic axial spondyloarthritis

Rinvoq helps to reduce back pain including back pain at night, stiffness and inflammation in your spine. These effects can help you to do normal daily activities and may improve your health-related quality of life.

Ankylosing spondylitis

Rinvoq helps to reduce back pain including night back pain, stiffness and inflammation in your spine. These effects can help you to do normal daily activities and so improve your health-related quality of life.

Ulcerative colitis

Rinvoq helps to control inflammation and reduce the signs and symptoms of ulcerative colitis, which can help you do normal daily activities and

improve your health-related quality of life.

Crohn's Disease

Rinvoq helps to control inflammation and reduce the signs and symptoms of Crohn's disease including frequent and loose stools, abdominal pain, and the inflammation of your intestinal lining. These effects can enable your normal daily activities, reduce fatigue, and improve your health-related quality of life.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Patients 65 years of age and older maybe at increased risk of infections, heart problems, including heart attack, and some types of cancer. Your doctor will discuss with you if Rinvoq is appropriate for you.

Rinvoq is not recommended for use in children under 12 years of age or weighing less than 40 kg with atopic dermatitis. This is because it has not been studied in this age group.

Rinvoq is not recommended for use in children and adolescents under 18 years of age with rheumatoid arthritis, psoriatic arthritis, non-radiographic axial spondyloarthritis, ankylosing spondylitis, ulcerative colitis and Crohn's disease. This is because it has not been studied in this age group.

Before you take Rinvoq

When you must not take it

Do not take Rinvoq if you have an allergy to:

- any medicine containing upadacitinib
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- chest tightness
- wheezing or difficulty breathing
- feeling faint or dizzy
- swelling of the face, lips, tongue or throat
- rash, itching or hives on the skin.

If any of these symptoms occur during treatment with Rinvoq, stop taking Rinvoq and get emergency medical help right away.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Return out-of-date or damaged medicines to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- you have an infection, or if you have ever had an infection that keeps coming back.

Rinvoq can reduce your body's ability to fight infections, may make an infection you already have worse, or make it more likely for you to get a new infection.

- you have or have had tuberculosis (TB), or you have been in close contact with someone who has had tuberculosis.

You may need tests to check for TB before you start taking Rinvoq.

Tell your doctor if you develop a persistent cough, fever, night sweats and weight loss during treatment with Rinvoq as these can be signs of TB.

- you have or have had a herpes infection (shingles)

Rinvoq may allow it to come back.

Tell your doctor if you develop a painful skin rash with blisters during your treatment with Rinvoq, as these can be signs of shingles.

- you have or have had hepatitis B or hepatitis C.
- you have, or have had, cancer.
- you smoke, or have smoked in the past.
- you are at high risk of developing skin cancer. Your doctor may recommend preventive measures such as regular skin examinations while taking Rinvoq. Talk to your doctor if you develop a new lesion or any change in the appearance of an area on the skin
- you have, or have had, heart problems, high blood pressure, or high cholesterol
- you have liver problems, or your liver does not work as well as it should.
- have kidney problems or worsening of previous kidney problems.
- you have unexplained stomach (abdominal) pain, have or have had diverticulitis (painful inflammation of small pockets in the lining of your intestine) or ulcers in your stomach or intestines, or are taking non-steroidal anti-inflammatory medicines.

- you have recently been vaccinated or are scheduled for any immunisations.
Some vaccines should not be given while you are taking Rinvoq. Check with your doctor before you receive any immunisations.
- you have had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins.

Tell your doctor if you are pregnant or plan to become pregnant

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Based on animal studies, Rinvoq may harm your unborn baby. Your doctor or pharmacist can discuss with you the risks and benefits involved.

You should use effective contraception to avoid becoming pregnant while taking Rinvoq, and for at least 4 weeks after your last dose of Rinvoq. If you become pregnant during this time, you must talk to your doctor.

Tell your doctor if you are breast-feeding or plan to breastfeed.

You should not take Rinvoq while you are breastfeeding as it is not known if this medicine passes into breast milk.

You may need blood tests before you start taking Rinvoq, or while you are taking it. This is to check if you have a low red blood cell count (anaemia), low white cell count (neutropenia or lymphopenia), high cholesterol or high levels of liver enzymes.

If you have not told your doctor about any of the above, tell them before you start taking Rinvoq.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Rinvoq may interfere with each other. These include:

- medicines to treat fungal infections (such as ketoconazole, itraconazole, posaconazole or voriconazole)
- antibiotics to treat bacterial infections (such as clarithromycin or rifampicin)
- medicines used to treat neurological disorders (such as phenytoin)
- medicines that affect your immune system (such as azathioprine, cyclosporin, and tacrolimus)
- medicines that may increase your risk of gastrointestinal perforation such as a non-steroidal anti-inflammatory medicines (usually used to treat painful and/or inflammatory conditions of muscle or joints), and/or opioids (used to treat severe pain), and/or corticosteroids (usually used to treat inflammatory conditions)

These medicines may be affected by Rinvoq or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Rinvoq

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

You may be required to take this medicine together with other medicines to treat your condition.

How much to take

Depending on your condition, your doctor will tell you how many tablets to take and when.

How to take it

Swallow the tablets whole with a full glass of water.

Do not split, halve, crush, or chew the tablets.

Avoid food or drink containing grapefruit during treatment with Rinvoq as these may increase the risk of side effects by increasing the amount of upadacitinib in your body.

When to take it

Take your medicine at about the same time each day.

It will help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

It is important that you do not skip doses of Rinvoq.

If you miss a dose and it is less than 10 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to

taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Rinvoq.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Rinvoq

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (such as blood tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Rinvoq to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Rinvoq.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

It can be difficult to tell whether symptoms are effects of your condition, side effects of Rinvoq or side effects from other medicines you may be taking.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- symptoms that may suggest an infection in the nose or throat
- cough
- fever
- feeling sick in the stomach
- weight gain
- cold sores
- painful skin rash with blisters and fever
- acne
- inflammation (swelling) of the hair follicles
- flu (influenza)
- anaemia
- pain in your belly (abdomen)
- fatigue (feeling unusually tired and weak)

- headache
- rash or hives (urticaria)
- some types of skin cancers (non-melanoma-types)
- infection of the lung, which may cause breathlessness, raised temperature and a cough with mucus.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- Signs of a serious infection, such as:
 - fever, sweating or chills
 - feeling short of breath
 - warm, red or painful skin sores on your body
 - feeling tired
 - muscle aches
 - blood in your phlegm, or mucous
 - diarrhoea or stomach pain
 - cough
 - weight loss
 - burning when you pass urine or passing urine more often than normal.

The above list includes serious side effects that may require medical attention.

Signs of tuberculosis include persistent cough, weight loss, night sweats and fever.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, anaemia (low red blood cell count) neutropenia (low white blood cell count) or high levels of cholesterol in your blood or high levels of liver enzymes) can only be found when your doctor does tests from time to time to check your progress.

Refer to the Data Sheet for a full list of side effects.

After taking Rinvoq

Storage

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Store your tablets in the original blister in order to protect from moisture.

Do not store Rinvoq or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least 1.5 m above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Rinvoq 15 mg modified-release tablets are purple, biconvex oblong tablets, 14 x 8 mm and debossed with 'a15' on one side.

Rinvoq 30 mg modified-release tablets are red, biconvex oblong tablets, 14 x 8 mm and debossed with 'a30' on one side.

Rinvoq 45 mg modified-release tablets are yellow to mottled yellow, biconvex oblong tablets, 14 x 8 mm and debossed with 'a45' on one side.

The tablets are provided in blisters. Each blister card contains 7 tablets. Each pack contains 7 or 28 tablets.

Ingredients

Rinvoq contains 15 mg, 30 mg or 45 mg of upadacitinib as the active ingredient.

It also contains the following:

- microcrystalline cellulose
- mannitol
- tartaric acid,
- hypromellose
- colloidal anhydrous silica
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide (E171)
- macrogol
- talc
- iron oxide black (E172) (15 mg only)
- iron oxide red (E172)
- iron oxide yellow (E172) (45 mg only).

This medicine does not contain gluten or lactose.

Sponsor

Rinvoq is distributed in New Zealand by:

AbbVie Limited

6th Floor, 156-158 Victoria St

Wellington, 6011

New Zealand

This leaflet was prepared in

August 2023.

Version 11

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