

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

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 moderate to severe active rheumatoid arthritis, which is an autoimmune disease that causes pain and swelling in the joints.

A family of enzymes known as Janus Kinase (JAK) creates signals in the body's immune system that result in inflammation. Upadacitinib belongs to a group of medicines called JAK inhibitors. It works to block these signals, thereby reducing inflammation and the production of immune cells.

In rheumatoid arthritis, RINVOQ helps to reduce signs and symptoms,

including joint pain, tenderness, stiffness and swelling in your joints.

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.

It is not known if RINVOQ is safe and effective in children under 18 years of age.

Before you take RINVOQ

When you must not take it

Do not take RINVOQ if you are already using any biological (injectable) medicines that depress the immune system or other medicines used to strongly suppress your immune system including azathioprine, cyclosporine and tacrolimus.

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
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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 zoster infection (chicken pox/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 cancer including skin cancer and lymphomas.
- you have liver problems, or your liver does not work as well as it should.
- 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. 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 breastfeeding 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 (neutropaenia or lymphopaenia), 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.

RINVOQ should not be used in combination with the following medicines:

- medicine that affects your immune system (e.g., azathioprine, cyclosporin and tacrolimus)
- biological medicines that affect your immune system (e.g., etanercept and adalimumab)
- medicine called JAK inhibitors used to treat rheumatoid arthritis (e.g., baricitinib and tofacitinib)

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

- medicines to treat fungal infections (e.g., ketoconazole, itraconazole, posaconazole or voriconazole)

- antibiotics to treat bacterial infections (e.g., clarithromycin or rifampicin)
- medicines used to treat neurological disorders (e.g., phenytoin)
- Some vaccines should not be given while you are taking RINVOQ. Check with your doctor before you receive any immunisations.

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

Your doctor will tell you how many tablets to take and when.

The usual dose is one 15 mg RINVOQ tablet once every day with or without food.

How to take it

Swallow the tablets whole with a full glass of water.

Do not split, crush, or chew the tablets.

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.

Your doctor may ask you to temporarily stop your RINVOQ if you develop a serious infection or if your blood tests results are outside of the normal range.

Your doctor will tell you when and how you can restart your medicine.

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 Poisons Information Centre (telephone 13 11 26) for advice, 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.

Tell your doctor if you notice any new spots on your skin, a spot that looks different, a sore that doesn't heal, a mole or freckle that has changed size, shape, colour or bleeds.

Wear sunscreen and a hat when outdoors and avoid getting sunburnt.

Your doctor will conduct regular skin checks for any suspicious spots.

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

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.

Tell your doctor as soon as possible if you have persistent cough, weight loss, night sweats and fever.

These are signs of tuberculosis.

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

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

People with rheumatoid arthritis or problems with their immune system are at increased risk of cancer, including lymphoma (symptoms include swelling of the glands in the neck, armpit or groin).

Some of these side effects (for example, anaemia (low red blood cell count) neutropaenia (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 Product Information 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 window sill 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.

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

Ingredients

RINVOQ contains 15 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
- macrogol
- talc
- ferrosulfate (E172)
- iron oxide red (E172).

This medicine does not contain gluten or lactose.

Distributor

RINVOQ is distributed in Australia by:

AbbVie Pty Ltd

ABN 48156 384 262
241 O'Riordan Street
MASCOT NSW 2020

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