

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I taking Rinvoq?

Rinvoq contains the active ingredient upadacitinib. Rinvoq is used to treat moderate to severe active rheumatoid arthritis, moderate to severe active psoriatic arthritis, active ankylosing spondylitis, active non-radiographic axial spondyloarthritis, moderate to severe atopic dermatitis, moderate to severe active ulcerative colitis and moderate to severe active Crohn's disease. For more information, see Section [1. Why am I taking Rinvoq?](#) in the full CMI.

2. What should I know before I take Rinvoq?

Check the list of ingredients at the end of the CMI. Do not take Rinvoq if you have ever had an allergic reaction to any of them. Do not take Rinvoq if you are already using a biological medicine or a medicine that depresses or strongly suppresses the immune system including azathioprine, ciclosporin and tacrolimus. Talk to your doctor before you take this medicine if you have any other medical conditions, you are a current or past long-time smoker, take any other medicines or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take Rinvoq?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rinvoq and affect how it works or Rinvoq may interfere with other medicines and affect how they work. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Rinvoq?

- the usual dose is one tablet once every day.
- do not split, crush, or chew the tablets. Swallow them whole with a full glass of water with or without food.

More instructions can be found in Section [4. How do I take Rinvoq?](#) in the full CMI.

5. What should I know while taking Rinvoq?

Things you should do	• remind any doctor, pharmacist or dentist you visit that you are taking Rinvoq. • keep all your appointments, including blood tests. • tell your doctor if you develop an infection, or pain or swelling in the leg, or pain in your chest and/or have difficulty breathing, or severe stomach pain especially accompanied by fever, nausea and vomiting.
Things you should not do	• do not stop taking this medicine or change the dose unless your doctor tells you to.
Driving or using machines	• do not drive or use machines if you experience a spinning sensation (vertigo) when taking Rinvoq until it resolves.
Drinking alcohol	• there is no information on the effects of taking Rinvoq with alcohol.
Looking after your medicine	• store Rinvoq in a cool dry place, below 30°C, away from moisture, heat and sunlight. • keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while taking Rinvoq?](#) in the full CMI.

6. Are there any side effects?

The more serious side effects include serious infections, e.g., tuberculosis, pneumonia, shingles, and blood clots. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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.

WARNINGS:

Speak with your doctor and refer to Section 2 for more information if:

- You have a history of cardiovascular disease (such as heart attack, stroke or blood vessel disease) or factors that increase your risk of cardiovascular disease.
- You are a current or past long-time smoker.
- You have or have had cancer including skin cancer and cancer of the lymph glands.
- You are 65 years of age and older.

Your doctor has prescribed RINVOQ because they believe it is the most suitable option for your condition and they have thought carefully about your specific needs and other ways to treat it.

Rinvoq[®] (rin voke)

Active ingredient: upadacitinib (yu-pa-da-si-ti-nib)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Rinvoq. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Rinvoq.**

Where to find information in this leaflet:

1. [Why am I taking Rinvoq?](#)
2. [What should I know before I take Rinvoq?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take Rinvoq?](#)
5. [What should I know while taking Rinvoq?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking Rinvoq?

Rinvoq contains the active ingredient upadacitinib, which is a Janus Kinase (JAK) inhibitor. JAK enzymes create signals in the body's immune system that result in inflammation. Rinvoq works to block these signals, thereby reducing inflammation and the production of immune cells within the body.

Rinvoq is used to treat:

- moderate to severe, active rheumatoid arthritis by helping to reduce signs and symptoms of inflammation, including joint pain, tenderness, stiffness and swelling in your joints.
- moderate to severe, active psoriatic arthritis by helping to reduce pain, stiffness, swelling in and around 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.
- active ankylosing spondylitis by helping to reduce back pain including night back pain, stiffness and inflammation in your spine.
- moderate to severe atopic dermatitis by improving the condition of your skin and reducing itching and flares.

Rinvoq has also been shown to improve symptoms of pain, anxiety, and depression associated with atopic dermatitis. Rinvoq can also help improve your sleep disturbance and overall quality of life.

- active non-radiographic axial spondyloarthritis in adults, a disease that primarily causes inflammation in the spine. 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.

- moderate to severe active ulcerative colitis by helping to control inflammation and reduce the signs and symptoms of ulcerative colitis, including bloody stools, abdominal pain and the need to rush to and the number of times you go to the toilet, helping you do normal daily activities, reduce fatigue and improve your health-related quality of life.

- moderate to severe active Crohn's disease by helping 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. Rinvoq can also help improve your ability to do your normal daily activities, reduce fatigue and improve your health-related quality of life.

2. What should I know before I take Rinvoq?

Warnings

Do not take Rinvoq if:

1. you are already using a biological medicine, including etanercept, adalimumab
2. you are taking other medicine used to strongly suppress your immune system, e.g., azathioprine, ciclosporin and tacrolimus
3. you are allergic to upadacitinib, or any of the ingredients listed at the end of this CMI. Symptoms of an allergic reaction (such as rash (hives), trouble

breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat), have been seen in people taking Rinvoq. Some of these reactions may be serious. If any of these symptoms occur during treatment with Rinvoq, stop taking Rinvoq and get emergency medical help right away.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives, or dyes.
- take any medicines for any other condition.
- have an infection or have 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. If you have diabetes, or are 65 years of age or older, you may have an increased chance of getting infections.
- have or have had tuberculosis, have been in close contact with someone who has had tuberculosis, or you have lived or travelled overseas where tuberculosis is a problem. You may need to have a test to check if you have previously been exposed to tuberculosis.
- have or have had shingles or chicken pox.
- have or have had hepatitis B, are a carrier of the hepatitis B virus or you think you may be at risk of contracting hepatitis B or hepatitis C.
- have been recently vaccinated or are scheduled for any immunisations such as against herpes zoster. Live vaccines should not be given while you are taking Rinvoq.
- have had blood clots, for example in the legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism) or have an increased risk for developing blood clots (for example: if you had recent major surgery, if you use hormonal contraceptives / hormonal replacement therapy, if a blood clotting disorder is identified in you or your close relative).
- are a current or past long-time smoker.
- have or have had cancer including skin cancer and lymphomas (cancer of the lymph glands).
- If you are at high risk of developing skin cancer, your doctor may recommend preventative measures or monitoring, such as regular skin examinations while taking Rinvoq. Talk to your doctor if you develop a new skin lesion or any change in the appearance of an area on the skin.
- have or have had an abnormal blood cell count such as low red blood cell count, low haemoglobin, low white cell count.
- have or have had heart problems, high blood pressure or high cholesterol.
- have or have had kidney or liver problems.
- 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.
- Repeatedly see a tablet or tablet pieces in your stool.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information on side effects including signs and symptoms under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Make sure your doctor is aware if you are pregnant or plan to become pregnant. Use effective contraception to avoid becoming pregnant while taking Rinvoq and for at least 4 weeks after your last dose of Rinvoq. Rinvoq should not be used during pregnancy. Based on animal studies, Rinvoq may harm your unborn baby.

Make sure your doctor is aware if you are breastfeeding or plan to do so. You should not take Rinvoq while you are breastfeeding. It is not known if this medicine passes into your breast milk.

Use in children

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

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 these patients.

Use in the elderly

Patients 65 years of age and older may be at increased risk of infections, heart problems including heart attack, stroke and some types of cancer.

3. What if I am taking other medicines?

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

Some medicines may interfere with Rinvoq and affect how it works.

Do not take Rinvoq if you are taking any of the following medicines:

- biological medicines.

Medicines that may increase the effect of Rinvoq include:

- medicines used to treat or prevent fungal infections, e.g., ketoconazole, itraconazole, posaconazole or voriconazole
- medicines used to treat infections caused by bacteria (antibiotic), e.g., clarithromycin.

Medicines that may reduce the effect of Rinvoq include:

- medicines used to treat tuberculosis and other bacterial infections, e.g., rifampicin
- medicines used to treat neurological disorders, e.g., phenytoin.

Medicines that may increase the risk of infection when taken with Rinvoq include:

- other JAK inhibitors, e.g., tofacitinib and baricitinib
- biological medicines, e.g., etanercept, adalimumab, see above list of medicines to avoid while taking Rinvoq
- medicines used for suppressing the immune system, e.g., azathioprine, ciclosporin, tacrolimus.

Medicines that may increase your risk of GI perforations:

- Medicines that may increase your risk of gastrointestinal perforation such as a non-steroidal anti-inflammatory medicine (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).

Medicines that may increase the risk of hypoglycaemia when taken with Rinvoq:

- Rinvoq may affect your blood sugar levels when you are taking medicines to treat diabetes. It is very important to talk to your doctor or pharmacist if you are taking medicines to treat diabetes or if you have diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking Rinvoq.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Rinvoq.

4. How do I take Rinvoq?

How much to take

If you have rheumatoid arthritis, psoriatic arthritis, non-radiographic axial spondyloarthritis or ankylosing spondylitis:

- take one 15 mg tablet once every day.

If you have atopic dermatitis:

- take one 15mg or 30 mg tablet once every day as prescribed by your doctor.
- your doctor may increase or decrease your dose depending on how well the medicine is working.
- if you are 65 years of age or older, the recommended dose is 15 mg a day.
- if you are an adolescent aged 12 years of age or older, the recommended dose is 15 mg a day.

If you have ulcerative colitis:

When starting treatment (Induction):

- take one 45 mg tablet once every day for 8 weeks, as prescribed by your doctor. This can be continued for another 8 weeks, for a total of 16 weeks (induction dose).

Continuing treatment (Maintenance):

- then take one 15 mg or 30 mg tablet once every day, as prescribed by your doctor (maintenance dose).
- your doctor may increase or decrease your dose depending on how well the medicine is working.

- if you are 65 years of age or older, the recommended maintenance dose is 15 mg a day.

If you have Crohn's disease:

When starting treatment (Induction):

- take one 45 mg tablet once every day for 12 weeks, as prescribed by your doctor (induction dose).

Continuing treatment (Maintenance):

- then take one 15 mg or 30 mg tablet once every day, as prescribed by your doctor (maintenance dose).
- Your doctor may increase or decrease your dose depending on how well the medicine is working.
- If you are 65 years of age and older, the recommended maintenance dose is 15 mg a day.

How to take Rinvoq

Do not split, crush or chew the tablets. Swallow them whole with a full glass of water.

- it does not matter if you take this medicine before or after food.
- follow the instructions provided and use Rinvoq until your doctor tells you to stop.
- in some instances, Rinvoq needs to be taken with other medicines. Your doctor will let you know which medicines, how to take them and how long to take them.
- Avoid food or drink containing grapefruit during treatment with Rinvoq as these may interact and increase the risk of side effects.

When to take Rinvoq

- take Rinvoq at about the same time each day.

Please look for the QR code on the medicine pack. Scan this code for more information on Rinvoq.

If you forget to take Rinvoq

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

If you miss a dose, take it as soon as you remember as long as it is at least 10 hours before your next dose.

If you forget your dose for an entire day, just skip the missed dose and take only a single dose as usual the following day.

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

If you take too much Rinvoq

You should immediately:

- phone the Poisons Information Centre in Australia (**by calling 13 11 26**), in New Zealand the National Poisons Centre (by calling 0800 POISON or 0800 764 766) or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appear to be no signs of discomfort or poisoning.

5. What should I know while taking Rinvoq?

Things you should do

- keep all your appointments so your progress can be checked.
- keep your appointments for blood tests to make sure the medicine is working and as some side effects are seen in blood results before you have any symptoms.
- get regular skin checks, and wear sunscreen and a hat when outdoors.
- remind any doctor, pharmacist or dentist you visit that you are taking Rinvoq.

Call your doctor straight away if you:

- Become pregnant while taking Rinvoq.

Things you should not do

- do not stop taking this medicine or change the dose without checking with your doctor.

Driving or using machines

Do not drive or use machines if you experience a spinning sensation (vertigo) when taking Rinvoq until it resolves.

Drinking alcohol

There is no information of the effects of taking Rinvoq with alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight, for example:

- do not store it in the bathroom or near a sink, and
- do not store it in the car or on windowsills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Upper airways: • sore or scratchy throat • blocked or runny nose • flu Gut: • feeling sick in the tummy • pain in your belly Body as a whole: • fever • weight gain • feeling unusually tired or weak • anaemia • headache • a spinning sensation (vertigo) Skin: • acne • cold sores • redness and swelling of the hair follicles • hives • rash • warts (skin papilloma)	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Signs of a serious infection: • fever, sweating or chills • feeling short of breath • feeling tired or lacking energy • muscle aches • diarrhoea • tummy pain • cough • weight loss • burning when passing urine or passing urine more often Signs of a blood disorder: • swelling of the glands in your neck, armpits or groin Skin: • painful skin rash with blisters • new, or changes to any skin spots, sores, or lesions • cluster of warm, red or painful skin sores or blisters on your body Signs of GI perforation (hole in the bowel): • sudden onset of stomach pain	Call your doctor straight away if you notice any of these serious side effects.

Serious side effects	What to do
- fever or chills - nausea or vomiting	
Signs of an allergic reaction: - difficulty breathing or swallowing - chest tightness - wheezing - severe dizziness or light-headedness - swelling of face, lips, tongue, or throat - severe itching of skin, with a red rash or raised bumps Signs of tuberculosis: - fever, night sweats - chills - difficulty breathing - a bad cough that won't go away - blood in your phlegm - weight loss Signs of the effect of a blood clot: - leg pain or tenderness - redness or discolouration in the leg or arm - swelling of the leg or arm - chest pain or pain in the upper back - sudden shortness of breath or difficulty breathing Signs of pneumonia: - fever, chills - cough sometimes with phlegm - feeling tired or lacking energy - shortness of breath - chest pain Signs of a heart attack: - chest pain or discomfort - lightheadedness, nausea, or vomiting - pain in jaw, neck or back - pain or discomfort in arm or shoulder - shortness of breath Signs of a stroke: - trouble speaking or difficulty understanding speech - sudden numbness, weakness or paralysis in the face, arm or leg of one side of the body - problems seeing in one or both eyes - headache - trouble walking	Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Rinvoq contains

Active ingredient (main ingredient)	Upadacitinib
Other ingredients (inactive ingredients)	- microcrystalline cellulose - hypromellose - mannitol - tartaric acid - colloidal anhydrous silica - magnesium stearate - polyvinyl alcohol - macrogol 3350 - talc - titanium dioxide - iron oxide red - iron oxide black (15 mg only) - iron oxide yellow (45 mg only)

Do not take this medicine if you are allergic to any of these ingredients.

Rinvoq does not contain gluten or lactose.

What Rinvoq looks like

Rinvoq 15 mg tablets are purple oblong tablets, 14 x 8 mm and marked 'a15' on one side (AUST R 312687).

Rinvoq 30 mg tablets are red oblong tablets, 14 x 8 mm and marked 'a30' on one side (AUST R 346215).

Rinvoq 45 mg tablets are yellow to mottled yellow oblong tablets, 14 x 8 mm and marked 'a45' on one side (AUST R 375857).

Rinvoq is supplied in blister packs inside a carton containing 7 or 28 tablets.

Who distributes Rinvoq?

AbbVie Pty Ltd

ABN 48 156 384 262

241 O'Riordan Street

MASCOT NSW 2020

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