

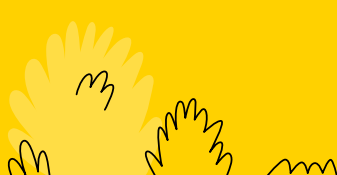
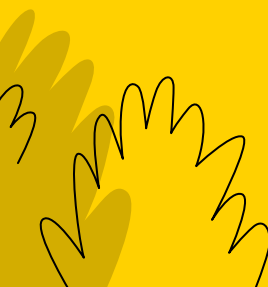


Starting your **RINVOQ[®]** (upadacitinib) **treatment journey**



A guide to your new treatment
for **inflammatory bowel
disease** (IBD)

For more information and useful
resources, visit **rinvoq.com.au** and
enter the access code **ASPIRE**



Why RINVOQ and why now?

It can be challenging and overwhelming to live with a chronic (long-term) condition like IBD.

IBD is a term used to describe two main conditions: Crohn's disease (CD) and ulcerative colitis (UC). These diseases cause inflammation and damage to the gastrointestinal tract, and they can also affect your whole body and every aspect of your life, from being able to meet a friend for lunch to feeling comfortable at work.

Before now, you may have received other medicines for your IBD. However, you may not have responded adequately to them. Therefore, your doctor has decided to prescribe RINVOQ for your condition.

This booklet contains additional information about your RINVOQ treatment and aims to answer some of the questions you may have.

*For more information and useful resources, visit **rinvoq.com.au** and enter the access code **ASPIRE***

This booklet is supplementary to the Consumer Medicine Information (CMI). Always refer to the CMI before starting RINVOQ treatment. You can find this by scanning the QR code at the back of this booklet or online at www.rinvoq.com.au.

Speak to your healthcare professional if you have any questions about your treatment.



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What is RINVOQ?

RINVOQ is a **once-daily tablet** used to treat different inflammatory conditions, including adults with moderate to severe active **CD** and **UC**.

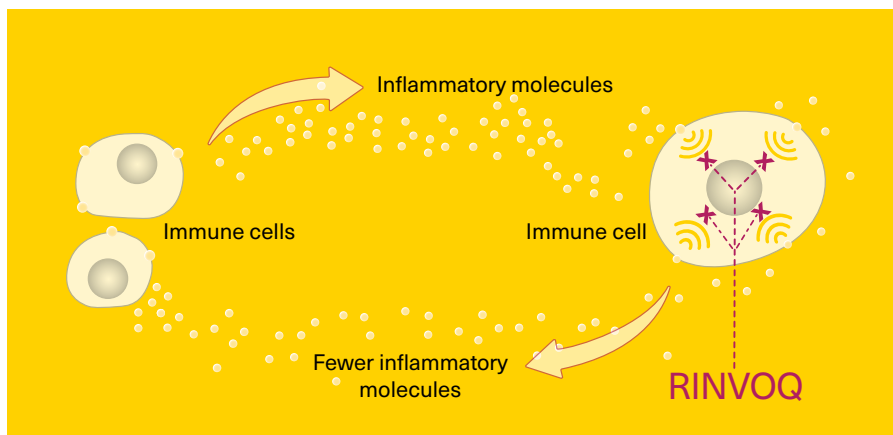
RINVOQ is available in:



Remember, your healthcare team is here to help. This could be your doctor, pharmacist, nurse or prescribing specialist. You can also get support from your family or friends if you feel like you need somebody to talk to.

How does RINVOQ work?

RINVOQ contains the active ingredient **upadacitinib**. It belongs to a group of medicines called **Janus kinase (JAK) inhibitors**. RINVOQ works by decreasing the activity of an enzyme called 'Janus kinase' in the body. In doing so, RINVOQ helps to reduce inflammation.



How can RINVOQ help me?

By decreasing the activity of Janus kinase, RINVOQ may help to improve:

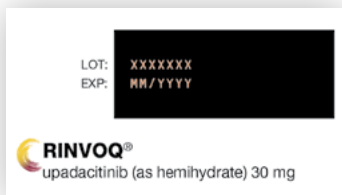
In CD:	In UC:
Frequent and loose stools	Frequent and bloody stools
Abdominal pain	Abdominal pain
Inflammation of the intestinal lining	The need to rush to the toilet
Ability to do normal daily activities	Ability to do normal daily activities
Fatigue	Fatigue

Inflammatory conditions are chronic conditions, so to help control your symptoms, you should take RINVOQ exactly as prescribed by your doctor.

Important reminders

Do not take RINVOQ:

- ⊗ If you are taking a biological medicine or another medicine used to strongly suppress your immune system, including azathioprine, ciclosporin and tacrolimus.
- ⊗ If you are allergic to upadacitinib, or any of the ingredients in RINVOQ as listed on the last page of the Consumer Medicine Information.
- ⊗ After the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.



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



Before taking RINVOQ

Speak to your doctor if you:

Have allergies to any other medicines, foods, preservatives or dyes.

Take any medicines for any other conditions.

Have or have had an infection that keeps coming back.

Have diabetes or are 65 years of age or older.

Have or have had tuberculosis (TB), have been in close contact with someone with TB, have lived or travelled overseas where TB is a problem.

Have or have had a chicken pox/shingles infection.

Have or have had hepatitis B, are a carrier of the hepatitis B virus, or think you may be at risk of contracting hepatitis B or hepatitis C.

Recently had or plan to have a vaccination (immunisation).

Have or have had cancer, including skin cancer and lymphomas (cancer of the lymph glands).

Review the Consumer Medicine Information (CMI) for a full list of things to watch out for before starting your RINVOQ treatment. You can access the CMI by scanning the QR code on the back of this booklet or at **rinvoq.com.au** by entering the access code **ASPIRE**.

Because:

Your doctor will discuss with you if RINVOQ treatment is appropriate for you.

Some medicines may interfere with RINVOQ and affect how it works. See the 'RINVOQ and other medicines' section to learn more.

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

This may increase the risk of getting infections while on RINVOQ. Patients 65 years of age and older may also have an increased risk of heart problems, including heart attack, stroke and some types of cancer.

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

RINVOQ may allow it to come back. Tell your doctor if you get a painful skin rash with blisters during RINVOQ treatment, as these can be signs of shingles.

Your doctor will factor this into their monitoring process.

Some vaccines, such as live vaccines, should not be given while you are taking RINVOQ. Check with your doctor before you receive any immunisations.

Your doctor will factor this into their monitoring process.

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.

Before taking RINVOQ (cont.)

Speak to your doctor if you:

Have or have had blood clots or have an increased risk of developing blood clots (e.g. recent major surgery, use hormonal contraceptives / hormonal replacement therapy, or a family history of blood clotting disorder).

Are a current or past long-time smoker.

Have or have had altered blood cell counts, liver, kidney or heart problems, high blood pressure or high cholesterol.

Have unexplained stomach pain, have or have had diverticulitis or ulcers in your stomach or intestines, or are taking non-steroidal anti-inflammatory medicines.

Plan to become pregnant or are pregnant, or if you are breastfeeding or planning to breastfeed.

***If you have any questions or concerns,
speak to your doctor.***

Because:

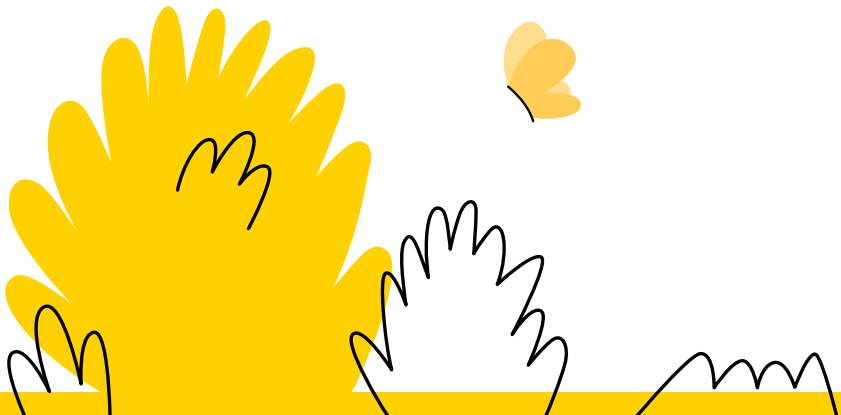
Your doctor will factor in your risk of blood clots when deciding if you can take RINVOQ.

Your doctor will discuss with you if RINVOQ treatment is appropriate for you.

You may need blood tests before you start taking and/or while taking RINVOQ. Your doctor will factor this into their monitoring process.

Your doctor will factor this into their monitoring process.

RINVOQ should not be taken during pregnancy or while breastfeeding.



RINVOQ and other medicines

Some medicines may interfere with RINVOQ and affect how well it works.

You should not take RINVOQ if you are using a biological medicine or other medicines that lower your immune system.



Some medicines that can affect the way RINVOQ works:

- Medicines to treat or prevent fungal infections
- Antibiotics to treat tuberculosis and other bacterial infections
- Medicines used to treat neurological disorders



Some medicines can increase the risk of infection when taken with RINVOQ:

- Other JAK inhibitors
- Biological medicines
- Medicines used to suppress the immune system



Some medicines that may increase your risk of gastrointestinal perforation:

- A non-steroidal anti-inflammatory medicine
- Opioids
- Corticosteroids

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. Do not stop taking your medicines or change the dose without checking with your doctor.

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



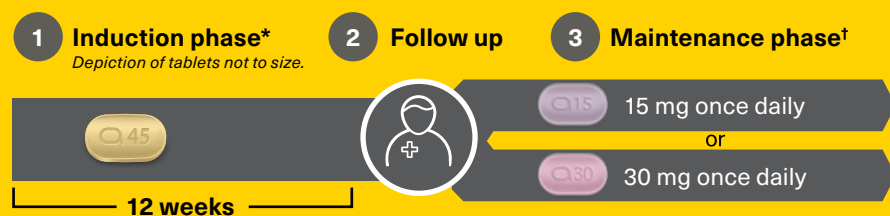
Taking RINVOQ for CD

Understanding your treatment plan

RINVOQ is a daily tablet administered in two phases: induction and maintenance.

During the induction phase, you will be prescribed RINVOQ 45 mg daily for **12 weeks**. You will then meet with your doctor to discuss how effective RINVOQ has been for you.

Depending on how you respond to RINVOQ, your doctor will set your daily dose for the maintenance phase (either 15 mg or 30 mg daily) or extend your induction phase for up to a further **12 weeks** (30 mg daily) as needed to reduce your disease activity.



Once on your maintenance dose, your doctor will continue to regularly review your treatment against your response as part of their monitoring process.

*Your induction dose may vary depending on your individual health circumstances. Your doctor will provide guidance on the appropriate dose for you.

†If you are 65 years or older, the recommended dose is 15 mg once a day for your ongoing treatment. Your doctor may reduce your dose if you have kidney problems or if you are prescribed certain other medicines.

Taking RINVOQ for UC

Understanding your treatment plan

RINVOQ is a daily tablet administered in two phases: induction and maintenance.

During the induction phase, you will be prescribed RINVOQ 45 mg daily for **8 weeks**. You will then meet with your doctor to discuss how effective RINVOQ has been for you.

Depending on how you respond to RINVOQ, your doctor will set your daily dose for the maintenance phase (either 15 mg or 30 mg daily) or extend your induction phase for up to a further **8 weeks** (45 mg daily) as needed to reduce your disease activity.



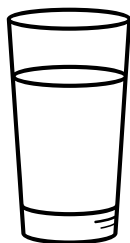
Once on your maintenance dose, your doctor will continue to regularly review your treatment against your response as part of their monitoring process.

*Your induction dose may vary depending on your individual health circumstances. Your doctor will provide guidance on the appropriate dose for you.

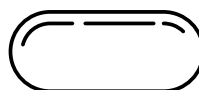
†If you are 65 years or older, the recommended dose is 15 mg once a day for your ongoing treatment. Your doctor may reduce your dose if you have kidney problems or if you are prescribed certain other medicines.

How to take RINVOQ

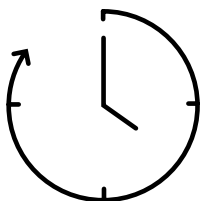
For the treatment of IBD, take RINVOQ as follows:



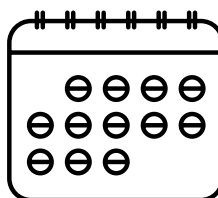
Take one tablet every day
with a full glass of water
(or as directed by your doctor)



As a whole tablet –
do not split, crush or chew it



At the same time each day –
with or without food



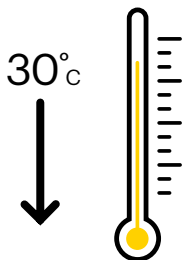
For as long as your doctor has
told you to – continue taking it
even if you feel better

Avoid food or drink containing grapefruit during treatment with RINVOQ as these may interact and increase the risk of side effects.

*Remind any doctor, pharmacist or dentist you visit
that you are taking RINVOQ.*

Looking after RINVOQ

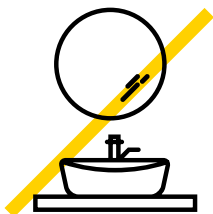
How to correctly store RINVOQ:



In a cool, dry place below 30°C (RINVOQ does not need to be refrigerated).

Keep your tablets in the original blister pack to protect them from moisture. Please talk to your pharmacist if RINVOQ is exposed to a temperature above 30°C.

Remember to consider the temperature when transporting your RINVOQ medication as well – don't leave your RINVOQ medication in a hot car.



Do not store RINVOQ in the bathroom, near a sink, on a windowsill or in the car. This is because these areas are not generally cool or dry and not below 30°C.



Keep RINVOQ where young children cannot reach it – a locked cupboard at least 1.5 metres off the ground is a good place to store medicines.

**Remember, do not take RINVOQ if the expiry date has passed.
If you need to throw your medicine away, do not throw it out in the household waste, ask your pharmacist how to correctly dispose of it.**

What you should know while taking RINVOQ

How much RINVOQ do I need to take?

RINVOQ is a tablet taken once daily, which comes in different dose strengths. Your doctor has prescribed the dose that is most appropriate to treat your IBD symptoms.

Always take your RINVOQ exactly as your doctor, nurse or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

What if I forget to take my dose?

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.

Can I miss a dose if my symptoms have improved?

Do not stop taking RINVOQ or miss a dose without first checking with your doctor. RINVOQ helps to control your condition but does not cure it. CD and UC are chronic (long-term) conditions and stopping or interrupting treatment may cause your condition to worsen, even if you are feeling better. It is important to keep taking your medicine as prescribed by your doctor, even if you feel well.

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

What if I take too much?

Immediately contact your doctor or the Poisons Information Centre (13 11 26) for advice or go to the Emergency Department at your nearest hospital, even if you are not experiencing any signs of discomfort or poisoning.

How does RINVOQ work?

RINVOQ helps to reduce the underlying inflammation causing your IBD symptoms and may work differently from other IBD medications you may be taking. Each medication you have been given plays a specific and defined role in your overall health. To get the most from your treatment plan, take all your medications as prescribed – always ask your doctor if you are unsure.

Will RINVOQ affect my ability to drive or use a machine?

A spinning sensation (vertigo) has been reported in some patients taking RINVOQ. Do not drive or use machines if you experience vertigo while taking RINVOQ until it resolves.

Can I drink alcohol while taking RINVOQ?

There is no information on the effects of taking RINVOQ with alcohol.



Possible side effects to look out for

Like all medicines, RINVOQ may cause side effects. However, everyone is different. Some people may experience side effects, and others may not. If you do experience any side effects, most are minor and temporary. However, some side effects may need medical attention. Make sure to tell your doctor, nurse or pharmacist as soon as possible if you start to feel unwell while taking RINVOQ.



Speak to your doctor if you have any of these **less serious side effects and they are worrying you**

- Sore or scratchy throat
- Blocked or runny nose
- Flu
- Feeling sick or pain in the tummy
- Weight gain
- Headache or fever
- Feeling unusually tired or weak
- Anaemia
- A spinning sensation (vertigo)
- Acne, cold sores, rash/hives, redness and swelling of the hair follicles





Call your doctor straight away if you notice any of these **serious side effects**

RINVOQ can reduce your body's ability to fight infection, which may mean you might be more susceptible to infection or an infection that you already have may worsen. In some cases, an infection can be life-threatening. **Tell your doctor as soon as possible** if you notice any of the following:

Signs of a serious infection

- Fever, sweating or chills
- Feeling short of breath
- Cough
- Feeling tired or lacking energy
- Muscle aches
- Diarrhoea
- Tummy pain
- 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 the body

Signs of gastrointestinal (GI) perforation (hole in the bowel)

- Sudden onset of stomach pain
- Fever or chills
- Nausea or vomiting

Possible side effects to look out for (cont.)



Go straight to the Emergency Department at your nearest hospital if you have any signs of these **very serious side effects**

Signs of an allergic reaction

- Difficulty breathing or swallowing
- Swelling of face, lips, tongue or throat
- Severe itching of skin, with a red rash or raised bumps
- Chest tightness, wheezing
- Severe dizziness or light-headedness

Stop taking RINVOQ if you experience any signs of an allergic reaction.

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

- Pain or tenderness in the leg
- Swelling, redness or discolouration in the leg or arm
- Chest pain or pain in the upper back
- Sudden shortness of breath or difficulty breathing

Signs of pneumonia

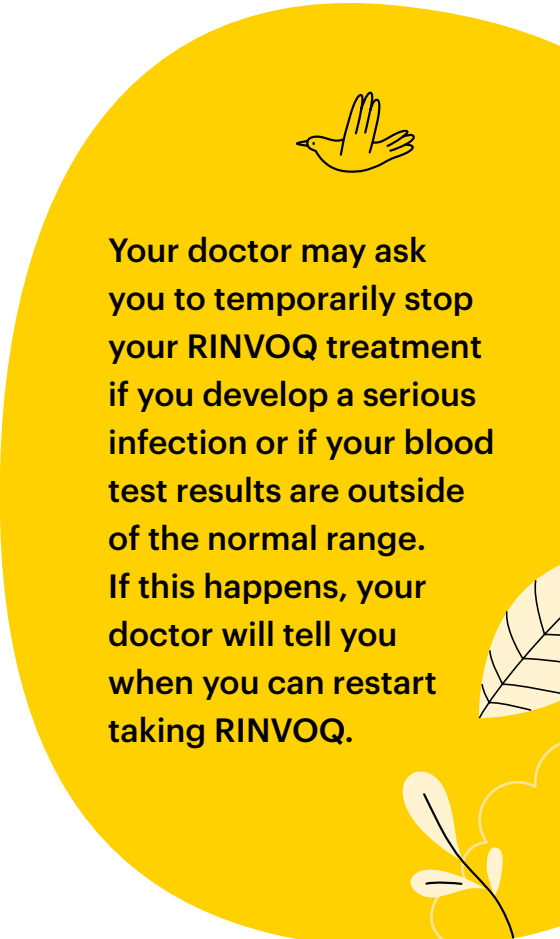
- Fever, chills
- Cough, sometimes with phlegm
- Feeling tired or lacking energy
- Shortness of breath
- Chest pain

Signs of a heart attack

- Chest pain or discomfort
- Lightheadedness, nausea, or vomiting
- Pain in the jaw, neck or back
- Pain or discomfort in the 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



Your doctor may ask you to temporarily stop your RINVOQ treatment if you develop a serious infection or if your blood test results are outside of the normal range. If this happens, your doctor will tell you when you can restart taking RINVOQ.

*For more details on possible side effects, review the Consumer Medicine Information by scanning the QR code on the back of this booklet, at **rinvoq.com.au** by entering the access code **ASPIRE**, or from your pharmacist.*

rinvoq.com.au

to learn more about your RINVOQ treatment

Visit **rinvoq.com.au** for practical tips and information about your RINVOQ treatment, including:



Frequently asked questions about RINVOQ



Tips for health and wellbeing, tailored to support people with inflammatory conditions



Medication management tips to assist you with setting important reminders for your RINVOQ treatment



Downloadable resources to support you on your treatment journey with RINVOQ

To find out more, visit **rinvoq.com.au** and enter the access code **ASPIRE**

This website provides general information for people who have been prescribed RINVOQ. It is not a substitute for advice given by a healthcare professional. Always talk to your doctor or pharmacist if you have concerns or questions about taking RINVOQ.



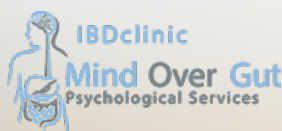
Other resources

The following external organisations provide resources and information for people living with IBD:



Crohn's & Colitis Australia (CCA) is a national non-profit organisation that works with people living with Crohn's disease and ulcerative colitis, healthcare professionals, governments, and the public to minimise the impact that these conditions have on the community.

crohnsandcolitis.org.au



IBDclinic is an online resource developed by Associate Professor Simon Knowles, a researcher and Clinical Psychologist from Melbourne, Australia. This website provides useful information and mental health support to people living with IBD.

ibd.mindovergut.com



Links to external websites are offered for your convenience. References to any products, services or other information by trademark or otherwise are not intended to imply endorsement by AbbVie Pty Ltd. Any healthcare information provided within these sources should be discussed with your healthcare professional and does not replace their advice.

You can access a copy of the the RINVOQ Consumer Medicine Information by scanning the QR code.





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