

Starting your **TREATMENT** journey with RINVOQ



**A guide for Inflammatory bowel disease (IBD)
patients who have been prescribed RINVOQ**

For more information visit
www.rinvoq.co.nz



The people shown are models.

Why RINVOQ and why now?

Before now, you may have received other medicines for your inflammatory bowel disease (IBD), which is a term used to describe two main conditions: Crohn's disease (CD) and ulcerative colitis (UC). However, you may not have responded adequately to them. Therefore, your doctor has decided to prescribe RINVOQ for your IBD.

This booklet contains additional information about your RINVOQ treatment and aims to answer any questions you may have. RINVOQ is an unfunded medicine for the treatment of CD and UC – you will need to pay for this medicine and other charges.

For more information and useful resources, visit www.rinvoq.co.nz



This booklet is supplementary to the Consumer Medicine Information. Always refer to the Consumer Medicine Information before starting RINVOQ treatment. You can find this online at www.rinvoq.co.nz or by scanning the QR code at the back of this booklet or on the product packaging.

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

Contents

04

Why RINVOQ?

06

Things you should know
before you take RINVOQ

08

Things to watch out for
before taking RINVOQ

10

Taking RINVOQ for IBD

14

What you need to know
about RINVOQ dosing

16

Possible side effects
to look out for

20

Tips on including RINVOQ
in your daily routine

22

www.rinvoq.co.nz
for things you need to know about
RINVOQ treatment

Why RINVOQ?

RINVOQ is a medication used to treat inflammatory bowel diseases (IBD), like Crohn's disease (CD) and ulcerative colitis (UC)*. Both of them cause inflammation of the digestive tract and can affect your normal daily activities.

You have been prescribed RINVOQ (otherwise known as upadacitinib) to treat your condition. Before being given RINVOQ, you may have been treated with other medicines. Your doctor or nurse will advise you which of these medicines you should continue to take with RINVOQ.

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. It has been prescribed to improve signs and symptoms that include abdominal pain, bowel urgency, bowel frequency, and fatigue.

RINVOQ is available in different doses. Your doctor will prescribe the dose that's right for you.



15 mg
modified-release tablets



30 mg
modified-release tablets



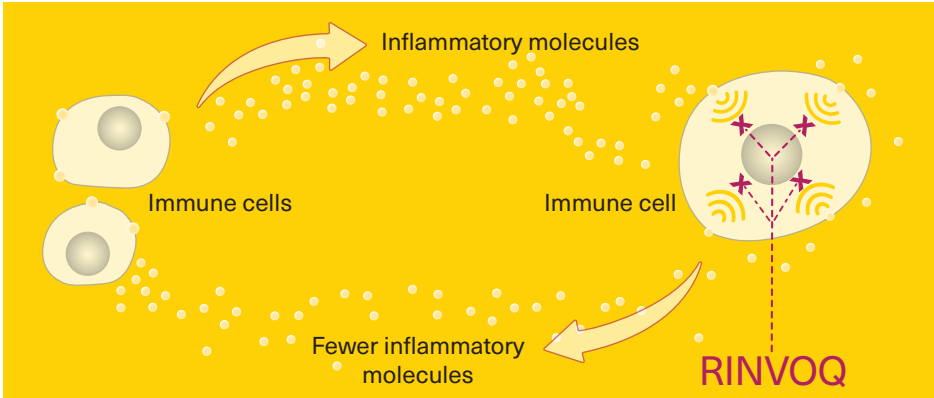
45 mg
modified-release tablets

*RINVOQ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

Remember, your healthcare team is here to help. This could be your GP, pharmacist, nurse, or rheumatologist. You can also get support from your family or friends if you're feeling like you need somebody to talk to.

How does RINVOQ work?

RINVOQ contains the active ingredient upadacitinib, which belongs to a group of medicines called Janus kinase (JAK) inhibitors. 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.



How can RINVOQ help me?

By reducing the activity of JAK, RINVOQ can help to improve:

In CD	In UC
<ul style="list-style-type: none">• Frequent and loose stools• Abdominal pain• Inflammation of the intestinal lining• Ability to do normal daily activities• Fatigue• Health-related quality of life	<ul style="list-style-type: none">• Frequent and bloody stools• Abdominal pain• The need to rush to the toilet• Ability to do normal daily activities• Fatigue• Health-related quality of life

Inflammatory conditions are chronic conditions. So to help control your symptoms, RINVOQ should be taken once daily, as prescribed by your doctor.

Things you should know before taking RINVOQ

Do not take RINVOQ:

- ❌ If you are allergic to any of the ingredients that RINVOQ has (see the last page of the Consumer Medicine Information for a full list of ingredients)
- ❌ After the expiry date printed on the pack or if the packaging is torn or shows signs of tampering
- ❌ If you have active tuberculosis or other serious infections
- ❌ If you are pregnant, planning to become pregnant, or breastfeeding. If you or your partner are planning on having children. Speak to your doctor or nurse about the risks and benefits involved while taking RINVOQ
- ❌ To treat any other complaints unless instructed by your doctor

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

Review the Consumer Medicine Information (available at www.rinvoq.co.nz) for a full list of things you should know before starting **RINVOQ** treatment.



RINVOQ and other medicines

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

You should not take RINVOQ if you are taking a biological medicine that lowers your immune system unless instructed by your prescriber to do so.

Some medicines that can affect the way RINVOQ works:

- ⚠ Medicines to treat or prevent 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 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)

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

- ⚠ Other JAK inhibitors (such as tofacitinib)
- ⚠ Biological medicines which suppress your immune system (such as etanercept and adalimumab)
- ⚠ Medicines used to suppress the immune system (such as azathioprine, ciclosporin and tacrolimus)

Check with your prescriber before taking these medicines with RINVOQ. 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.

In addition to medicines, avoid foods or drinks containing grapefruit during treatment with RINVOQ, as these may interact and increase the risk of side effects.

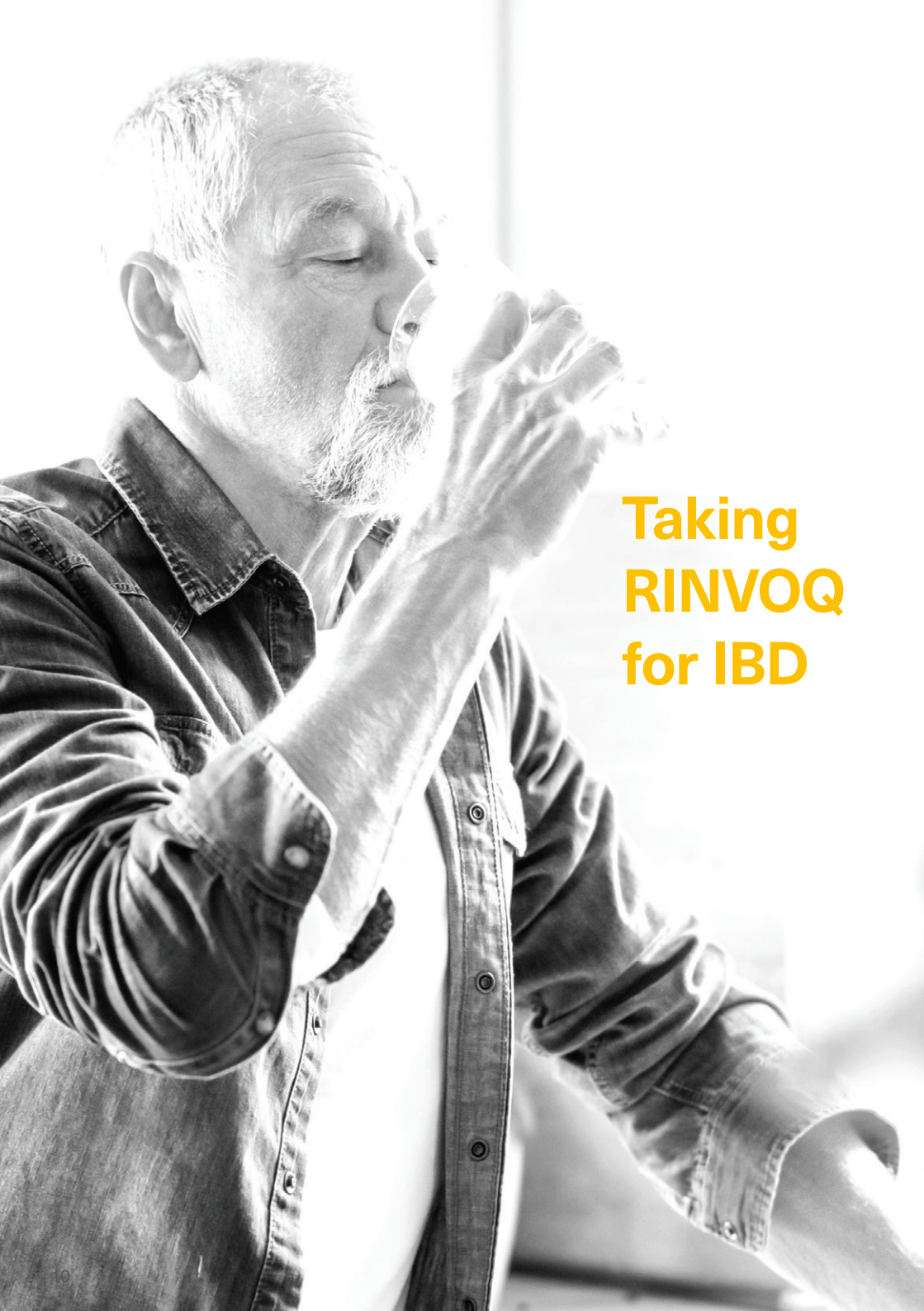


Things to watch out for before and during your RINVOQ treatment

Review the Consumer Medicine Information (available at www.rinvoq.co.nz) for a full list of things to watch out for before starting RINVOQ treatment. You should always take all the medicines that have been prescribed for you. Do not stop taking the medicine or change the dose without checking with your doctor. Ask your doctor, pharmacist, or nurse if you have any questions.

Speak to your doctor if you have: **Because:**

Allergies to any other medicines, foods, preservatives, or dry eyes.	Your doctor will discuss with you if RINVOQ treatment is appropriate for you.
An infection, or if you have ever had an infection that keeps coming back.	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.
Tuberculosis (TB), a history of TB, have been in close contact with someone with TB or have lived or travelled overseas where TB is a problem.	You may need tests to check for TB before you start taking RINVOQ.
A herpes zoster infection or have had a herpes zoster infection (chicken pox or shingles).	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.
Have had hepatitis B or C or are a carrier of the hepatitis B or C virus.	Your doctor will factor this into their monitoring process.
Recently had or plan to have a vaccination (immunisation).	Some vaccines, such as live vaccines, should not be given while you are taking RINVOQ. Check with your doctor before you receive any immunisations.
Had cancer, including skin cancer and lymphomas.	You should tell your doctor if you notice any new or changed spots on your skin. Your doctor will decide if you can still be given RINVOQ.
Had blood clots, for example, in the legs (deep vein thrombosis) or lungs (pulmonary embolism).	See your doctor immediately if you experience signs of blood clots, such as a painful swollen leg, shortness of breath, or chest pain.
Liver or kidney problems, or if you have high cholesterol or altered blood cell counts.	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), a low white cell count (neutropaenia or lymphopaenia), high cholesterol, or high levels of liver enzymes, and your kidney function.
Plans to become pregnant, your partner has plans to become pregnant, or you or your partner are pregnant, breastfeeding, or are planning to breastfeed.	Your doctor will discuss with you the risks and benefits of RINVOQ treatment. RINVOQ should not be taken during pregnancy or while breastfeeding.
Have, or have had, heart problems, high blood pressure, or high cholesterol.	You may need blood tests before you start taking RINVOQ or while you are taking it. This is to check for high cholesterol levels.
You smoke or have smoked in the past.	Your doctor will decide if RINVOQ is right for you.
65 years of age or older.	You may be at increased risk of infections, heart problems, including heart attacks, and some types of cancer. Your doctor will discuss with you if RINVOQ is appropriate for 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 antiinflammatory medicines.	Your doctor will discuss whether RINVOQ is right for you.



**Taking
RINVOQ
for IBD**

For the treatment of CD RINVOQ is a daily tablet administered in two phases: induction and maintenance.

The recommended starting dose for RINVOQ is 45 mg once a day for 12 weeks. You will then meet with your doctor for a follow-up visit to discuss how effective it was.

The usual maintenance dose is 15 mg. In certain cases, your doctor may consider a maintenance dose of 30 mg instead. Your doctor will prescribe the dose that's right for you.



*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 of age 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.

For the treatment of UC

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

The recommended starting dose for RINVOQ is 45 mg once daily for 8 weeks.[§] After the induction period, the recommended maintenance dose is 15 mg. In certain cases, your doctor may consider a maintenance dose of 30 mg instead. Your doctor will prescribe the dose that's right for you.



[§]The induction phase may be extended for up to 16 weeks as needed to reduce your disease activity. Your doctor will determine how long your induction phase should be at your follow-up visit.

*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 of age 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:



One tablet (15 mg, 30mg, or 45mg) as prescribed every day with a full glass of water



At the same time each day – with or without food

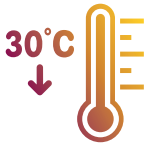


As a whole tablet – do not split, crush or chew it



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

How to store RINVOQ:



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

Store 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.



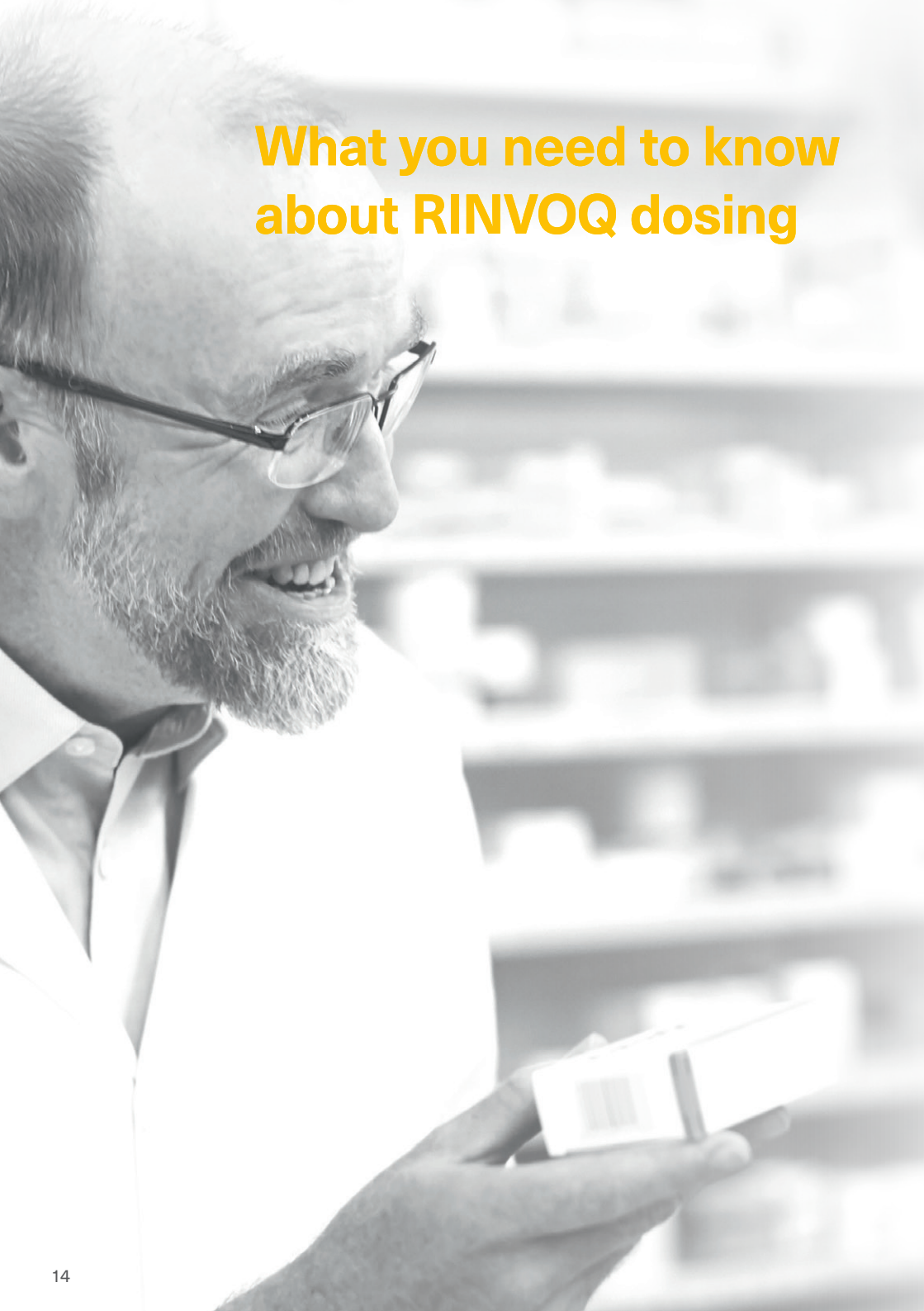
Do not store RINVOQ in the bathroom, near a sink, on a window sill or in the car.



Out of the sight and reach of children – 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 need to know about RINVOQ dosing



How much RINVOQ do I need to take?

RINVOQ is a tablet taken once daily that 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 miss a dose?

Take it as soon as you remember as long as it is at least 10 hours before your next dose. Otherwise, skip the dose you missed and take your next dose when you are meant to.

What if I forget my dose for the entire day?

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 a forgotten tablet.

Can I miss a dose if my symptoms have improved?

No. Do not stop taking RINVOQ or miss a dose unless your doctor has told you to. RINVOQ helps control your condition but does not cure it. IBD is a chronic condition, and stopping or interrupting treatment may cause your symptoms to worsen, even if you are feeling better. It is important to keep taking your medicine, even if you feel well.

What if I take too much?

Immediately contact your doctor or the National Poisons Centre (0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, even if you are not experiencing any signs of discomfort or poisoning.

How is RINVOQ different from other medications I am taking?

RINVOQ helps reduce the underlying inflammation causing your symptoms and may work differently to other 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 if you are unsure.

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

It is not expected that RINVOQ will have an effect on your ability to drive or use machines.

Can I drink alcohol while taking RINVOQ?

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

Possible Side Effects

Like all medicines, RINVOQ can cause side effects. However, everyone is different. Some people may experience side effects, and others may not. 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

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

Skin:

- Acne
- Cold sores
- Redness and swelling of the hair follicles
- Hives
- Rash

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

RINVOQ can reduce your body's ability to fight infection, and make an infection that you already had worse, or make it more likely that you get a new infection. In some cases, the 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
- 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
- Nausea or vomiting
- Fever or chills

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
- Chest tightness
- Wheezing
- Severe dizziness or lightheadedness
- 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 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

For more details on possible side effects, review the Consumer Medicine Information (available at www.rinvoq.co.nz). 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.

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.

Tips on including RINVOQ in your daily routine

Pick the right time for you



You should take RINVOQ at the same time every day, so picking a time that suits you is important. Taking RINVOQ straight after one of your everyday activities (such as brushing your teeth) can help. You don't need to plan your medication around your meal time. RINVOQ can be taken with or without food.



Create a self-care ritual

Add taking RINVOQ to the time you dedicate to looking after yourself, such as after meditation or a 10 minute stretching session.



Set a reminder

Set up a reminder on your phone or on a calendar somewhere visible to help you to remember to take RINVOQ every day.

You could always ask a family member to remind you too – having more than one reminder can be helpful.



Stay motivated

Don't lose sight of why you are taking RINVOQ – stick to a routine and form good habits to help you get the most out of your treatment.

How long does it take to build a routine? One research study suggests it can take an average of 66 days for a behaviour to become automatic. See the next page for a tool to help you with your RINVOQ Routine.

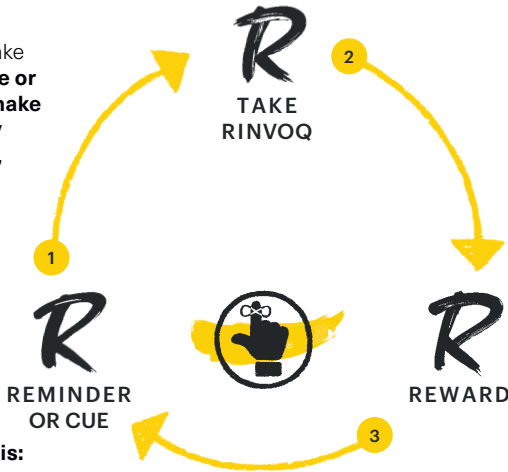
My RINVOQ Routine

A regular routine helps to remind you to take your RINVOQ pill each day, as prescribed by your HCP. Before long, it will be a natural part of your day.

My Personal Goal: _____

Choose something that is meaningful to you that you'd like to work toward.

It's easy to forget to take your pill. **A simple cue or reminder can help make it a part of your daily routine.** For example, place your pill bottle next to your tea bags.



Connecting a reinforcement right after taking a pill can help to build a daily routine.

Do something you enjoy such as sitting down with a cup of your favourite tea.

My reminder or cue is:

My reward is:



Create a good back-up plan. Weekends and travel can make sticking to your routine a challenge. It can help to have back-up reminders that would work in those situations.

My back-up plan is:

Inflammatory conditions, such as IBD, are chronic. So to help control your symptoms, RINVOQ should be taken exactly as prescribed by your doctor.

Useful Resources for IBD

The following external organisations provide a wealth of resources and information for people living with IBD.

New Zealand Resources

Crohn's & Colitis New Zealand

A charitable trust that aims to provide support, advice, resources, and education on Crohn's disease and ulcerative colitis.

crohnsandcolitis.org.nz

Health Navigator New Zealand

The Health Navigator website provides one place for New Zealanders to find reliable and trustworthy health information and self-care resources. It focuses on promoting clear, consistent messages that enable users to get the information they need at the time they need it.

[Healthnavigator.org.nz](http://healthnavigator.org.nz)

Visit **www.rinvoq.co.nz** – for things you need to know about your RINVOQ treatment



This website provides general information for people who have been prescribed RINVOQ. It is not a substitute for advice given by a healthcare professional.

Overseas Resources

Please note that treatment available in other countries may not be available in New Zealand.

Crohn's & Colitis UK

UK's charity for Crohn's and Colitis. Since 1979, the organisation has aimed to improve the lives of those with Crohn's disease and ulcerative colitis by providing information, support, and funding research initiatives.

crohnscolitisfoundation.org/

Crohn's & Colitis Foundation

The Crohn's & Colitis Foundation is an American nonprofit organisation. They provide education, support, and advocacy programs to patients and caregivers. Additionally, the foundation educates health professionals to improve the quality of care provided to patients.

www.versusarthritis.org

Crohn's and colitis Australia

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

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

Important information about RINVOQ

RINVOQ is a prescription medicine containing upadacitinib hemihydrate and is available as modified release tablets each equivalent to 15 mg, 30mg or 45mg of upadacitinib. It is used for the treatment of moderate to severe active rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis, active non-radiographic axial spondyloarthritis, moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease in adults, and moderate to severe atopic dermatitis in adults and adolescents 12 years and older.

RINVOQ has risks and benefits. Do not use RINVOQ if you have: an allergy to any medicines containing upadacitinib or any of the other ingredients in RINVOQ listed in the Consumer Medicines Information (CMI). Do not take the medicine after the expiry date. Before you use RINVOQ, tell your doctor if you have (or have had): allergies to any medicines, foods, preservatives or dyes; an infection or a history of infections that keep coming back; tuberculosis, or you have been in close contact with someone who has had tuberculosis; herpes infection (shingles); hepatitis B or C; cancer or at high risk of developing skin cancer; heart problems, high blood pressure or high cholesterol; smoked or are currently a smoker; liver problems; kidney problems; blood clots in the veins of your legs or lungs; unexplained stomach pain, have or have had diverticulitis or ulcers in your stomach or intestines, or are taking non-steroidal anti-inflammatory medicines; recently received or plan to receive a vaccine (patients taking RINVOQ should not receive live vaccines); are pregnant or plan on becoming pregnant; or are breastfeeding or plan to breastfeed. You may need blood tests before you start taking RINVOQ, or while you are taking it. Tell your doctor if you are 65 years of age or older. Tell your doctor as soon as possible if you notice 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 mucus, diarrhoea/stomach pain, cough, weight loss, burning when you pass urine or passing urine more often than normal. Tell your doctor immediately or go to your nearest hospital if you take too much RINVOQ (overdose), even without discomfort or signs of poisoning. Tell your doctor and other health care professionals: if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines may affect RINVOQ how well it works, or they may be affected by RINVOQ. Avoid food or drink containing grapefruit. Tell all doctors, dentists and pharmacists who are treating you that you are using RINVOQ. Common side effects: Tell your doctor if you feel unwell while taking RINVOQ. The more common side effects of RINVOQ include; throat or nose infection; cough; fever; feeling sick in the stomach; weight gain; cold sores; painful skin rash with blisters and fever; acne; swelling of the hair follicles; flu; anaemia; pain in your belly; fatigue; headache; rash/hives.

If you have any questions about using RINVOQ, including the risks and benefits, how much to use, how and when to use it, or the storage conditions, ask your healthcare professional and refer to the Consumer Medicine Information (CMI) available from <https://www.medsafe.govt.nz/Consumers/CMI/r/rinvoq.pdf> or freephone 0800 900 030. Ask your doctor if RINVOQ is right for you. Use strictly as directed. If symptoms continue, or you have side effects, see your doctor, pharmacist or healthcare professional.

RINVOQ is fully funded under Special Authority for the treatment of eligible patients with rheumatoid arthritis – normal pharmacy prescription charges apply. RINVOQ is not funded for psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, atopic dermatitis, ulcerative colitis and Crohn's disease - you will need to pay the full cost of this medicine. Normal pharmacy and doctor's charges will apply. RINVOQ-Min-CMI, v11, 16 August 2023.



**You can access a copy of the
Consumer Medicine Information
(CMI) by scanning the QR code.**

<https://www.abbvie.ie/nz-rin-cmi>