



A guide for for rheumatology patients who have been prescribed RINVOQ

for more information visit www.rinvoq.co.nz



Why RINVOQ and why now?

Before now, you may have received other medicines for your rheumatoid arthritis (RA), psoriatic arthritis (PsA) or ankylosing spondylitis (AS). However, you may not have responded adequately to them. Therefore, your doctor has decided to prescribe RINVOQ for your inflammatory condition.

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

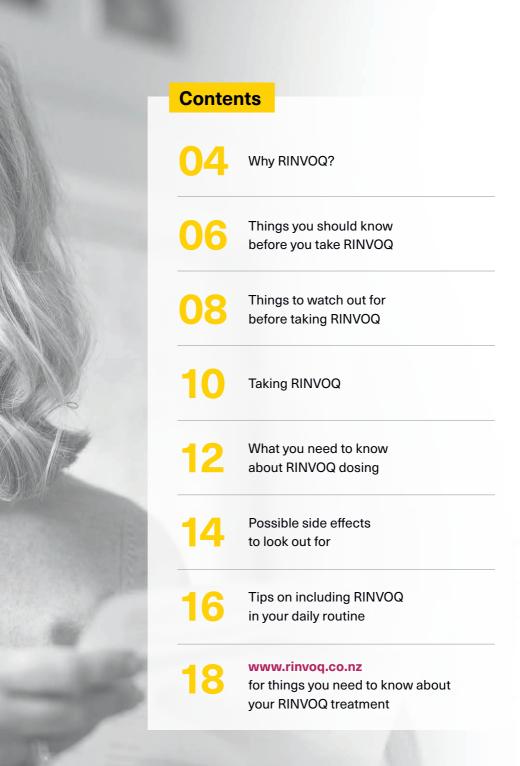


For more information and useful resources, visit www.rinvoq.co.nz



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.



Why RINVOQ?

RINVOQ is a medication used to treat the inflammatory conditions, rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS).

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

What is RINVOQ?

RINVOQ is a 15mg dose, once-daily tablet that targets the underlying inflammation that can cause the signs and symptoms of your condition. These symptoms include:

RA – joint pain, tenderness, stiffness and swelling in your joints

PsA – pain, stiffness, swelling in and around joints, pain and stiffness in your spine, psoriatic skin rash and tiredness

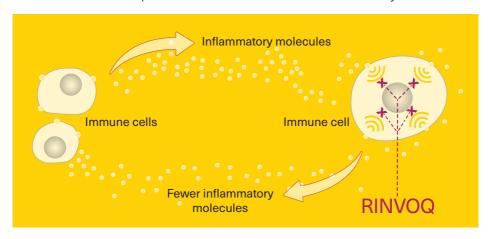
AS – back pain including night back pain, stiffness and inflammation in your spine.



Remember, your healthcare team are 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 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.



How can RINVOQ help me?

By reducing the activity of Janus Kinase, RINVOQ can help to reduce:

RA	PsA	AS
Joint pain & tenderness Stiffness in your joints Swelling in your joints Slow down damage to the bone and cartilage	Pain Stiffness Swelling in and around your joints Pain and stiffness in your spine Psoriatic skin rash Tiredness Slow down damage to the bone and cartilage	Back pain including night back pain Stiffness and inflammation in your spine

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

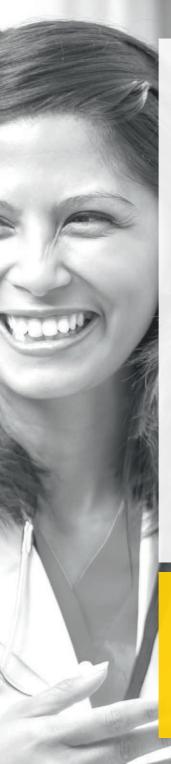
Things you should know before taking RINVOQ

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 your doctor tells you to

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 antiinflammatory 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)



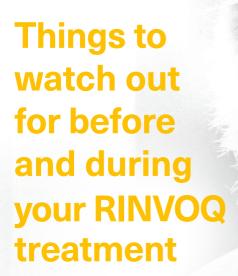
Biological medicines which suppress your immune system. (such as etanercept and adalimumab)



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 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.

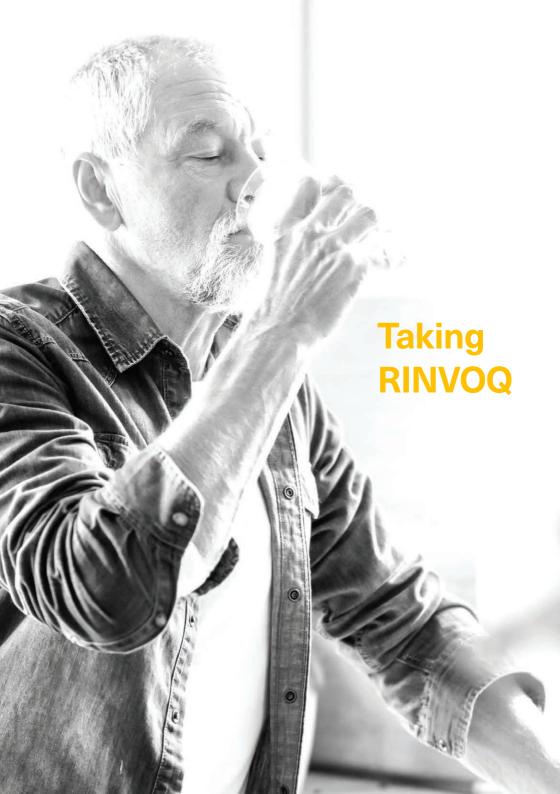


You should always take all the medicines that have been prescribed for you. Do not stop taking a medicine or change the dose without checking with your doctor. Ask your doctor, pharmacist or nurse if you have any questions.

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.

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

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 herpes zoster infection (chicken pox/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 DVT) 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), low white cell count (neutropaenia or lymphopaenia), high cholesterol or high levels of liver enzymes.
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.
Patients over 65 years of age and older.	May be 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.
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.	Your doctor will discuss whether RINVOQ is right for you.
Have diabetes.	If you are taking any medicines to treat diabetes, your doctor may decide on how much to take while taking RINVOQ.



For the treatment of RA, PsA and AS take RINVOQ as follows:



One 15mg tablet 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.

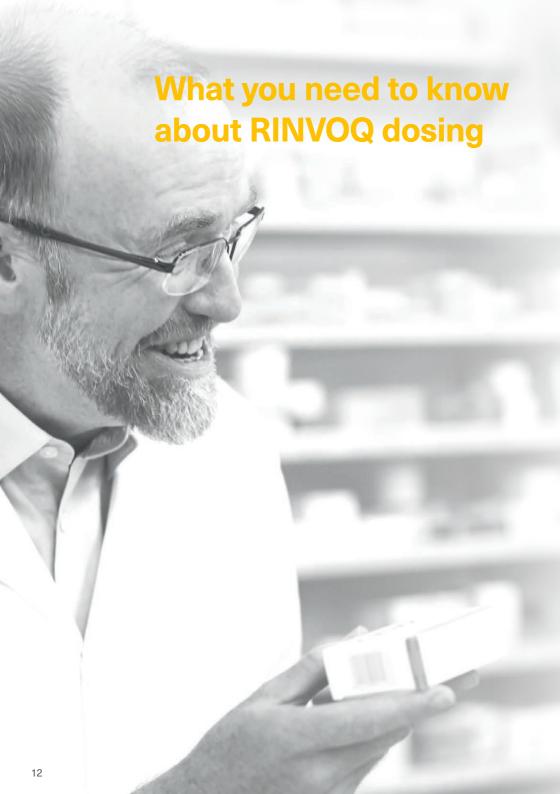


Do not store RINVOQ in the bathroom, near a sink, on a window sill or in the car.



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 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 to control your condition but does not cure it. Rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS) are chronic conditions 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.

I used to take an injection for my inflammatory condition, why am I now taking a tablet?

You may have previously been on a medicine for your inflammatory condition that required injections. The active ingredient of RINVOQ is provided in tablet form.

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 to look out for

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

- · Sore or scratchy throat
- · Blocked or runny nose
- Fever
- Cough
- Feeling sick in the tummy

- Weight gain
- Acne
- Cold sores
- Painful skin rash with blisters

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
- Cough
- Warm, red or painful skin sores on your body
- Feeling tired or lacking energy
- Muscle aches

- Diarrhoea
- Tummy pain
- Weight loss
- Burning when passing urine or passing urine more often
- Blood in phlegm or mucous

Signs of tuberculosis include

- Persistent cough
- Weight loss

- Night sweats
- Fever

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

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

Signs of the effect of a blood clot

- · Painful swollen leg
- Chest pain

Shortness of breath

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 Connecting a your pill. A simple cue or reinforcement right reminder can help make after taking a pill it a part of your daily can help to build a routine. For example. daily routine. place your pill bottle Do something you next to your tea bags. enjoy such as sitting down with a cup of your favourite tea. REMINDER OR CUE 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:

RA, PsA and AS are chronic inflammatory conditions. It's important to remember to take your treatment daily as prescribed, even if you are feeling well. Taking RINVOQ every day keeps the levels of medicine in your body stable to give it the best chance of being successful in treating your condition.

Useful Resources for inflammatory conditions

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

New Zealand Resources

Arthritis New Zealand

A national voluntary organisation which represents the interests of those with arthritis. It contains information on the condition and its treatment.

www.arthritis.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.

www.healthnavigator.org.nz

New Zealand Rheumatology Association

The New Zealand Rheumatology Association (NZRA) is the organisation that represents the rheumatologists of New Zealand. You can use this resource to find a Rheumatologist near you.

www.rheumatology.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.

Arthritis Australia

An Australian national organisation which represents the interests of those with arthritis. You'll find information on the condition and its treatment.

www.arthritisaustralia.com.au

Arthritis UK

The United Kingdom's national organisation which represents the interests of those with arthritis. It offers information on the condition and its treatment.

www.versusarthritis.org

Arthritis Foundation USA

An American national organisation which represents the interests of those with arthritis. Find information on the condition and its treatment.

www.arthritis.org

Australian Rheumatology Association

The ARA is an association of rheumatologists in Australia that is a specialty society of the Royal Australasian College of Physicians (RACP). This website contains links to condition-specific information sheets from Arthritis Australia.

www.rheumatology.org.au

American College of Rheumatology

The American College of Rheumatology (ACR) is an ethically-driven, professional membership organization committed to improving the care of patients with rheumatic disease and advancing the rheumatology subspecialty. This site contains information for patients and caregivers.

www.rheumatology.org

Important information about RINVOQ

RINVOQ is a prescription medicine containing upadacitinib hemihydrate and is available as modified release tablets each equivalent to 15 mg, 30 mg or 45 mg of upadacitinib. It is used for the treatment of moderate to severe active rheumatoid arthritis, active psoriatic arthritis, active ankylosing spondylitis, active nonradiographic axial spondyloarthritis, moderately to severely active ulcerative colitis, moderately to severely active Crohn's disease in adults, moderate to severe atopic dermatitis in adults and adolescents 12 years and older, and giant cell arteritis in adults. 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 antiinflammatory medicines; recently received or plan to receive a vaccine (patients taking RINVOQ should not receive live vaccines); have diabetes; 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, warts (skin papillomas), feeling tired, muscle aches, blood in your mucous, diarrhoea/stomach pain, cough, weight loss, burning when you pass urine or passing urine more often than normal. If you repeatedly see your tablet or tablet pieces in your stools, check with your doctor. 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. If you are taking any medicines used to treat diabetes, your doctor may decide how much to take while taking 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; swelling of the feet & hands. 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 Criteria for the treatment of eligible patients with rheumatoid arthritis, atopic dermatitis, Crohn's disease & ulcerative colitis. RINVOQ is not funded for ankylosing spondylitis, giant cell arteritis, non-radiographic axial spondylarthritis & psoriatic arthritis. For these indications patient co-payment for this medicine and healthcare professional fee apply.



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

abbv.ie/nz-rin-cmi

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