

RINVOQ® 15 mg, 30mg & 45mg Extended-Release Film Coated Tablets

Upadacitinib (15 mg, 30 mg, 45 mg)

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What RINVOQ® is used for

RINVOQ® is used to treat adults with:

- moderately to severely active rheumatoid arthritis. Rheumatoid arthritis is a disease that causes inflamed joints.
- active psoriatic arthritis. Psoriatic arthritis is a disease that causes inflamed joints and psoriasis.
- non-radiographic axial spondyloarthritis. Non-radiographic axial spondyloarthritis is a disease that primarily causes inflammation in the spine.
- active ankylosing spondylitis. Ankylosing spondylitis is a disease that primarily causes inflammation in the spine.
- Giant cell arteritis
Giant cell arteritis is a disease that causes inflammation of the blood vessels generally affecting the medium and large arteries in the head, neck, and arms.
- ulcerative colitis
Ulcerative colitis is an inflammatory disease of the large bowel. RINVOQ® is used to treat adults with ulcerative colitis who did not respond well enough or did not tolerate previous therapy.

- Crohn's disease

Crohn's disease is an inflammatory disease that may involve any part of the digestive tract, but most commonly affects the bowel. RINVOQ® is used to treat adults with Crohn's disease who did not respond well enough or did not tolerate previous therapy.

RINVOQ® is used to treat adults and adolescents 12 years and older with moderate to severe atopic dermatitis, also known as atopic eczema. RINVOQ® may be used with eczema medicines that you apply to the skin or it may be used on its own.

How RINVOQ® works

RINVOQ® works by reducing the activity of an enzyme in the body called 'Janus kinase'.

Rheumatoid arthritis

RINVOQ® can help to reduce pain, stiffness and swelling in your joints, reduce tiredness, and it can slow down damage to the bone and cartilage in your joints. These effects can ease your normal daily activities and so improve your quality of life.

Psoriatic arthritis

RINVOQ® can help to reduce pain, stiffness, and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash, and tiredness, and it can slow down damage to the bone and cartilage in your joints. These effects can ease your normal daily activities and so improve your quality of life.

Atopic Dermatitis

Taking RINVOQ® can improve the condition of your skin and reduce itching and flares. RINVOQ can help improve symptoms of pain, anxiety and depression that people with atopic

dermatitis may have. RINVOQ can also help improve your sleep disturbance and overall quality of life.

Non-radiographic axial spondyloarthritis and Ankylosing spondylitis

RINVOQ® can help to reduce back pain, stiffness, and inflammation in your spine. These effects can ease your normal daily activities and so improve your quality of life.

Giant cell arteritis

RINVOQ® can help to control the signs and symptoms of giant cell arteritis including headache, scalp tenderness, jaw pain, and tiredness. These effects can help you to do normal daily activities and so improve your health-related quality of life.

Giant cell arteritis is often treated with medicines called steroids. They are usually effective, but can have side effects if used at high doses for a long time. Reducing the steroid dose can also lead to a flare of giant cell arteritis. Adding RINVOQ® to the treatment means that steroids can be used for a shorter time, while still controlling giant cell arteritis.

Ulcerative colitis

RINVOQ® can help to reduce the signs and symptoms of the disease including bloody stools, abdominal pain and the need to rush to and the number of times you go to the toilet. These effects can enable your normal daily activities and reduce fatigue.

Crohn's disease

RINVOQ® can help to reduce the signs and symptoms of the disease including the need to rush to and the number of times you go to the toilet, abdominal pain, and the inflammation of your intestinal lining. These effects

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can enable your normal daily activities and reduce fatigue

Before you use RINVOQ[®]

- When you must not use it

- if you are allergic to upadacitinib or any of the other ingredients
Symptoms such as rash (hives), trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat, that may mean you are having an allergic reaction have been seen in people taking RINVOQ[®]. Some of these reactions were serious. If any of these symptoms occur during treatment with RINVOQ[®], stop taking RINVOQ[®] and get emergency medical help right away.
- if you have a severe infection (such as pneumonia or bacterial skin infection)
- if you have active tuberculosis (TB)
- if you have severe liver problems
- if you are pregnant (see section Pregnancy, breast-feeding and contraception)

Pregnancy

RINVOQ[®] must not be used during pregnancy.

Breast-feeding

If you are breast-feeding or are planning to breast-feed, talk to your doctor before taking this medicine. You should not use RINVOQ[®] while breast-feeding as it is not known if this medicine passes into breast milk. You and your doctor should decide if you will breast-feed or use RINVOQ[®]. You should not do both.

Contraception

If you are a woman of child-bearing potential, you must use effective

contraception to avoid becoming pregnant while taking RINVOQ[®] and for at least 4 weeks after your last dose of RINVOQ[®]. If you become pregnant during this time, you must talk to your doctor straight away.

If your child has her first menstrual period while taking RINVOQ, you should inform the doctor.

- Before you start to use it

Talk to your doctor, pharmacist or nurse before and during treatment with RINVOQ[®] if:

- you have an infection (fever, sweating, or chills, shortness of breath, warm, red, or painful skin or sores on your body, feeling tired, cough, burning sensation when you pass urine or passing urine more often than normal, severe headache with stiff neck), or if you have ever had an infection that keeps coming back – RINVOQ[®] can reduce your body's ability to fight infections and so may worsen an infection that you already have, or make it more likely for you to get a new infection.
- you have had tuberculosis or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting RINVOQ[®] and may retest during treatment.
- you have had a herpes zoster infection (shingles), because RINVOQ[®] may allow it to come back. Tell your doctor if you get a painful skin rash with blisters as these can be signs of shingles.
- you have ever had hepatitis B or C.
- you have recently had or plan to have a vaccination (immunisation) - this is because

live vaccines are not recommended while using RINVOQ[®]

- you have or have had cancer, you smoke or have smoked in the past - because your doctor will have to decide if you can still be given RINVOQ[®]
- you are at high risk of developing skin cancer, your doctor may recommend preventive measures such as regular skin examinations while taking RINVOQ[®]. Talk to your doctor if you develop a new lesion or any change in the appearance of an area on the skin. Some patients receiving RINVOQ[®] have developed skin cancers.
- you have heart problems, high blood pressure, or high cholesterol.
- your liver does not work as well as it should.
- you have had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins.
- you have kidney problems or worsening of previous kidney problems.
- 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.
- you repeatedly see a tablet or tablet pieces in your stool.
- you have diabetes.

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You will need blood tests before you start taking RINVOQ®, or while you are taking it. This is to check for a low red blood cell count (anaemia), low white blood cell count (neutropaenia or lymphopaenia), high blood fat (cholesterol) or high levels of liver enzymes. The tests are to check that treatment with RINVOQ® is not causing problems.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some medicines may reduce how well RINVOQ® works or may increase the risk of getting side effects. It is very important to talk to your doctor or pharmacist if you are taking any of the following:

- medicines to treat fungal infections (such as itraconazole, posaconazole or voriconazole)
- medicines to treat bacterial infections (such as clarithromycin)
- medicines to treat Cushing's syndrome (such as ketoconazole)
- medicines to treat tuberculosis (such as rifampicin)
- medicines to treat seizures or fits (such as phenytoin)
- medicines that affect your immune system (such as azathioprine, 6-mercaptopurine, ciclosporin and tacrolimus)
- 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).

- medicines to treat diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking RINVOQ®.

If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before taking RINVOQ®.

How to use RINVOQ®

For oral use only.

- How much to use

- **Always take this medicine exactly as your doctor or pharmacist has told you.** Check with your doctor or pharmacist if you are not sure.

- When to use it

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

The recommended dose is one 15 mg tablet once a day.

If you have atopic dermatitis:

Adults:

The recommended dose is 15 mg or 30 mg once a day as prescribed by your doctor. Your doctor may increase or decrease your dose depending on how well the medicine is working.

Elderly:

If you are 65 years of age or older, the recommended dose is 15 mg once a day.

Adolescents (from 12 to 17 years of age) weighing at least 40 kg:

The recommended dose is 15 mg once a day.

If you have ulcerative colitis

The recommended dose is 45 mg once a day for 8 weeks. Your doctor may decide to extend the initial 45 mg dose for another 8 weeks (for 16 weeks total). This will be followed by 15 mg or 30 mg once a day for your long-term treatment. Your doctor may increase or decrease your dose depending on how you respond to the medicine.

Elderly:

If you are 65 years of age or older, the recommended dose is 15 mg once a day for your long-term treatment.

Your doctor may reduce your dose if you have kidney problems, or you are prescribed certain other medicines.

If you have Crohn's disease

The recommended dose is one 45 mg tablet once a day for 12 weeks. This will be followed by one 15 mg or one 30 mg tablet once a day for your long-term treatment. Your doctor may increase or decrease your dose depending on how you respond to the medicine.

Elderly:

If you are 65 years of age or older, the recommended dose is 15 mg once a day for your long-term treatment.

Your doctor may reduce your dose if you have kidney problems, or you are prescribed certain other medicines.

How to take:

- Swallow the tablet whole with water. Do not split, crush, chew or

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break the tablet before swallowing as it may change how much medicine gets into your body.

- To help you remember to take RINVOQ[®], take it at the same time every day.
- The tablets can be taken with or without food.

- How long to use it

- Do not stop taking RINVOQ[®] without first talking with your healthcare provider.
- It is important that you do not miss or skip doses of RINVOQ[®] during treatment.

- If you forget to use it

- 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 a forgotten dose.

- If you use too much (overdose)

If you take more RINVOQ[®] than you should, contact your doctor. You may get some of the listed side effects.

While you are using it

- Things you must do

Take RINVOQ[®] exactly as your healthcare provider tells you to take it. Do not change your dose.

- Things you must not do

Do not use RINVOQ[®] for a condition for which it was not prescribed.

Do not give RINVOQ[®] to other people, even if they have the same

symptoms that you have. It may harm them. 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.

- Things to be careful of **Elderly**

Patients 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.

Children and adolescents

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, giant cell arteritis, ulcerative colitis, and Crohn's disease. This is because it has not been studied in these patients.

Side effects

Like all medicines, RINVOQ[®] can cause side effects, although not everybody gets them.

Serious side effects

Talk to your doctor or get medical help immediately if you get any signs of infection such as:

- shingles or painful skin rash with blisters (herpes zoster) – common (may affect up to 1 in 10 people)
- infection of the lung (pneumonia), which may cause

shortness of breath, fever, and a cough with mucus - common (may affect up to 1 in 10 people)

- infection in the blood (sepsis) – uncommon (may affect up to 1 in 100 people)
- allergic reaction (chest tightness, wheezing, swelling of the lips, tongue or throat, hives) – uncommon (may affect up to 1 in 100 people)

Other side effects

Talk to your doctor if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people)

- throat and nose infection
- acne

Common (may affect up to 1 in 10 people)

- non-melanoma skin cancer
- cough
- fever
- cold sores (herpes simplex)
- feeling sick in the stomach (nausea)
- increase in an enzyme called creatine kinase, shown by blood tests
- low white blood cell counts shown in blood tests
- increased levels of cholesterol (a type of fat in the blood) as shown in tests
- increased levels of liver enzymes, shown by blood tests (sign of liver problems)
- weight gain
- inflammation (swelling) of the hair follicles
- flu (influenza)
- anemia
- pain in your belly (abdomen)

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- fatigue (feeling unusually tired and weak)
- headache
- hives (urticaria)
- urinary tract infection
- rash
- warts (skin papilloma)
- swelling of the feet and hands (peripheral edema)

Rare (may affect up to 1 in 1000 people)

- Changes in the colour of semen (mostly blue and less frequently green)

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of RINVOQ®

- Storage

Store RINVOQ® at or below 30°C.

Store RINVOQ® in the original container to protect it from moisture.

Keep RINVOQ® and all medicines out of the reach of children.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

RINVOQ® 15 mg extended-release tablets are purple, biconvex oblong tablets with dimensions of 14 x 8 mm and debossed with 'a15' on one side.

RINVOQ® 30 mg extended-release tablets are red biconvex oblong tablets with dimensions of 14 x 8 mm and debossed with 'a30' on one side.

RINVOQ® 45 mg extended-release tablets are yellow biconvex oblong, with dimensions of 14 x 8 mm, and debossed with 'a45' on one side

The tablets are provided in blisters.

Each calendar blister contains 7 tablets, each pack contains 28 tablets.

- Ingredients

Active ingredient: upadacitinib

Inactive ingredients:

microcrystalline cellulose, Hypromellose, mannitol, tartaric acid, silica (colloidal anhydrous) and magnesium stearate. Film coating contains polyvinyl alcohol, macrogol, talc, titanium dioxide (E171), black iron oxide (E172) (15 mg strength only), iron oxide yellow (E172) (45mg strength only) and iron oxide red (E172).

- MAL number:

RINVOQ® 15 mg extended-release tablets:

MAL20106001ARZ

RINVOQ® 30 mg extended-release tablets:

MAL23086004ARZ

RINVOQ® 45 mg extended-release tablets:

MAL24126009ARZ

Manufacturer

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Product Registration Holder

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MALAYSIA

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