

Package leaflet: Information for the patient

RINVOQ EXTENDED-RELEASE TABLET 15 MG RINVOQ EXTENDED-RELEASE TABLET 30 MG RINVOQ EXTENDED-RELEASE TABLET 45 MG

upadacitinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What RINVOQ is and what it is used for
2. What you need to know before you take RINVOQ
3. How to take RINVOQ
4. Possible side effects
5. How to store RINVOQ
6. Contents of the pack and other information

1. What RINVOQ is and what it is used for

RINVOQ contains the active substance upadacitinib. It belongs to a group of medicines called Janus kinase inhibitors. By reducing the activity of an enzyme called 'Janus kinase' in the body, RINVOQ lowers inflammation in the following diseases:

- Rheumatoid Arthritis
- Psoriatic Arthritis
- Non-radiographic Axial Spondyloarthritis
- Ankylosing Spondylitis
- Atopic Dermatitis
- Ulcerative Colitis

Rheumatoid Arthritis

RINVOQ is used to treat adults with rheumatoid arthritis. Rheumatoid arthritis is a disease that causes inflamed joints. If you have moderate to severe active rheumatoid arthritis, you may first be given other medicines, one of which will usually be methotrexate. If these medicines do not work well enough, you will be given RINVOQ either alone or in combination with methotrexate to treat your 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 is used to treat adults with psoriatic arthritis. Psoriatic arthritis is a disease that causes inflamed joints and psoriasis. If you have active psoriatic arthritis, you may first be given other medicines. If these medicines do not work well enough, you will be given RINVOQ either alone or in combination with methotrexate to treat your 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.

Non-radiographic Axial Spondyloarthritis

RINVOQ is used to treat active non-radiographic axial spondyloarthritis in adults. Non-radiographic axial spondyloarthritis is a disease that primarily causes inflammation in the spine. If you have active non-radiographic axial spondyloarthritis, you may first be given other medicines. If these medicines do not work well enough, you will be given RINVOQ to treat your non-radiographic axial spondyloarthritis.

RINVOQ can help to reduce back pain including back pain at night, stiffness, and inflammation in your spine. These effects can help you to do normal daily activities and so improve your health-related quality of life.

Ankylosing Spondylitis

RINVOQ is used to treat adults with ankylosing spondylitis. Ankylosing spondylitis is a disease that primarily causes inflammation in the spine. If you have active ankylosing spondylitis, you may first be given other medicines. If these medicines do not work well enough, you will be given RINVOQ to treat your ankylosing spondylitis.

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

Atopic Dermatitis

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.

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.

Ulcerative Colitis

RINVOQ is used to treat moderately to severely active ulcerative colitis in adults who did not respond well enough or did not tolerate previous therapy. Ulcerative colitis is an inflammatory disease of the large bowel.

RINVOQ can help to control inflammation and reduce the signs and symptoms of ulcerative colitis including bloody stools, abdominal pain and the need to rush to and the number of times you go to the toilet. These effects can enable your normal daily activities, reduce fatigue, and improve your health-related quality of life.

2. What you need to know before you take RINVOQ

Do not take RINVOQ

- if you are allergic to upadacitinib or any of the other ingredients of this medicine (listed in section 6). 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)

Warnings and precautions

Talk to your doctor or pharmacist 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 - 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 or have had 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 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 have fever and stomach-area pain that does not go away, and a change in your bowel habits.
- you have kidney problems.

Blood tests

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.

Elderly

There is a higher rate of infection in patients aged 65 years and older. Tell your doctor as soon as you notice any signs or symptoms of an infection.

Children and adolescents

RINVOQ is not recommended for use in children under 12 years of age or adolescents weighing less than 30 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 and ulcerative colitis. This is because it has not been studied in this age group.

Other medicines and RINVOQ

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, 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)

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

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.

Driving and using machines

RINVOQ has no effect on the ability to drive and use machines.

3. How to take RINVOQ

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

How much to take

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

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 as prescribed by your doctor once a day. 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 30 kg:

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

If you have ulcerative colitis

The recommended dose is one 45 mg tablet 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 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 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.
- 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.

If you take more RINVOQ than you should

If you take more RINVOQ than you should, contact your doctor. You may get some of the side effects listed in section 4.

If you forget to take RINVOQ

- If you miss a dose, take it as soon as you remember.
- 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 stop taking RINVOQ

Do not stop taking RINVOQ unless your doctor tells you to stop taking it.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible 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 straight away 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 – 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 infections
- acne

Common (may affect up to 1 in 10 people)

- 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)
- fatigue (feeling unusually tired and weak)
- headache
- rash
- some types of skin cancers (non-melanoma-types)
- urinary tract infection

Uncommon (may affect up to 1 in 100 people)

- thrush in the mouth (white patches in the mouth)
- increased levels of triglycerides (a type of fat) in the blood, as shown in tests

Not known (frequency cannot be estimated from available data):

- allergic reactions (chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips, tongue or throat, hives)

Reporting of side effects

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

5. How to store RINVOQ

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister label and carton after 'EXP'.

Store at or below 30°C.

Store in original blister to protect from moisture.

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.

6. Contents of the pack and other information

What RINVOQ contains

The active substance is upadacitinib.

RINVOQ 15 mg extended-release tablets

- Each extended-release tablet contains upadacitinib hemihydrate, equivalent to 15 mg upadacitinib.
- The other ingredients are:
 - Core tablet: microcrystalline cellulose, mannitol, tartaric acid, hypromellose, silica colloidal anhydrous, magnesium stearate.
 - Film coating: poly(vinyl alcohol), macrogol, talc, titanium dioxide (E171), iron oxide red (E172), iron oxide black (E172).

RINVOQ 30 mg extended-release tablets

- Each extended-release tablet contains upadacitinib hemihydrate, equivalent to 30 mg upadacitinib.
- The other ingredients are:
 - Core tablet: microcrystalline cellulose, mannitol, tartaric acid, hypromellose, silica colloidal anhydrous, magnesium stearate.
 - Film coating: poly(vinyl alcohol), macrogol, talc, titanium dioxide (E171), iron oxide red (E172).

RINVOQ 45 mg extended-release tablets

- Each extended-release tablet contains upadacitinib hemihydrate, equivalent to 45 mg upadacitinib.
- The other ingredients are:
 - Core tablet: microcrystalline cellulose, mannitol, tartaric acid, hypromellose, silica colloidal anhydrous, magnesium stearate
 - Film coating: poly(vinyl alcohol), macrogol, talc, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

What RINVOQ looks like and contents of the pack

RINVOQ 15mg extended-release tablets

RINVOQ 15 mg extended-release tablets are purple, oblong, biconvex tablets imprinted on one side with 'a15'.

RINVOQ 30 mg extended-release tablets

RINVOQ 30 mg extended-release tablets are red, oblong, biconvex tablets imprinted on one side with 'a30'.

RINVOQ 45 mg extended-release tablets

RINVOQ 45 mg extended-release tablets are yellow to mottled yellow, oblong, biconvex tablets imprinted on one side with 'a45'.

The tablets are provided in blisters.

RINVOQ is available in packs containing 28 extended-release tablets.
Each calendar blister contains 7 tablets.

Not all presentations may be available locally.

Product Owner

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