PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RINVOQ 15 mg prolonged-release tablets

RINVOQ 30 mg prolonged-release tablets

RINVOQ 45 mg prolonged-release tablets

Upadacitinib

Sugar free

Read all this leaflet carefully before you start taking RINVOQ

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- RINVOQ has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

This PIL is free of typographical and grammatical errors.

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
- Axial spondyloarthritis
    - Non-radiographic axial spondyloarthritis
    - Ankylosing Spondylitis (AS, radiographic axial spondyloarthritis)
- Giant cell arteritis
- Atopic Dermatitis
- Ulcerative colitis
- Crohn's disease

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.

Axial spondyloarthritis (*non-radiographic axial spondyloarthritis and ankylosing spondylitis*)

RINVOQ is used to treat adults with axial spondyloarthritis. Axial spondyloarthritis is a disease that primarily causes inflammation in the spine. If you have active 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 axial spondyloarthritis.

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 is used to treat adults with 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.

RINVOQ can help to control the signs and symptoms of giant cell arteritis including headache, scalp tenderness, jaw pain, and tiredness. These effects can ease your normal daily activities and so improve your 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 or if used 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.

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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

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.

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

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 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 can enable your normal daily activities and reduce fatigue.

2. What you need to know before you take RINVOQ

Do not take RINVOQ

- if you are hypersensitive (allergic) to upadacitinib or any of the other ingredients of RINVOQ (listed in section 6)
- 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)
- If you are breastfeeding your baby (see section Pregnancy, breastfeeding and contraception)

Warnings and precautions

This PIL is free of typographical and grammatical errors.

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. If you have diabetes or are 65 years of age or older you may have an increased chance of getting infections.
- 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 had in the past cancer, smoke or have smoked in the past, because your doctor will discuss with you if RINVOQ is appropriate for you
- non-melanoma skin cancer has been observed in patients taking RINVOQ. Your doctor may recommend that you have regular skin examinations while taking RINVOQ. If new

skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

- you have, or have had, heart problems because your doctor will discuss with you if RINVOQ is appropriate for you
- high blood pressure, or high cholesterol
- your liver does not work as well as it should
- you have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have an increased risk for developing this (for example: if you had recent major surgery, if you use hormonal contraceptives\hormonal replacement therapy, if a blood clotting disorder is identified in you or your close relatives). Your doctor will discuss with you if RINVOQ is appropriate for you.
  Tell your doctor if you get sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discolouration in the leg or arm as these can be signs of blood clots in the veins
- you have 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.

If you notice any of the following serious side effects, tell a doctor straight away:

- symptoms such as a rash (hives), trouble breathing, or swelling of your lips, tongue, or throat, you may be having an allergic reaction. Some people taking RINVOQ had

serious allergic reactions. If you have any of these symptoms during treatment with RINVOQ, stop taking RINVOQ and get emergency medical help straight away

- severe stomach pain especially accompanied by fever, nausea, and vomiting
- you repeatedly see a tablet or tablet pieces in your stool
- you have diabetes

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.

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 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 axial spondyloarthritis (non-radiographic axial spondyloarthritis and ankylosing spondylitis) , ulcerative colitis, or Crohn's disease. This is because it has not been studied in this age group.

Other medicines and RINVOQ

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional 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 or diverticulitis such as 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 or if you have 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.

Pregnancy, breastfeeding and contraception

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Pregnancy

RINVOQ must not be used during pregnancy.

Breastfeeding

If you are breastfeeding or are planning to breast-feed, talk to your doctor before taking this medicine. You should not use RINVOQ while breast-feeding. You and your doctor should decide if you will breast-feed or use RINVOQ. You should not do both.

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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

Do not share medicines prescribed for you with any other person.

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

If you have rheumatoid arthritis, psoriatic arthritis or axial spondyloarthritis (non-radiographic axial spondyloarthritis and ankylosing spondylitis) or giant cell arteritis.

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

If you have atopic dermatitis

Adults (from 18 to 64 years of age):

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.

Adolescents (from 12 to 17 years of age) weighing at least 30 kg:

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

Your doctor may increase your dose to one 30 mg tablet once a day 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.

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.

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 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.
- Do not swallow the desiccant.

- Avoid food or drink containing grapefruit whilst you are taking (or being treated with) RINVOQ as these may make side effects more likely, by increasing the amount of medicine 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

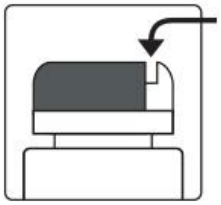
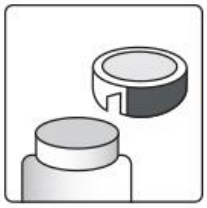
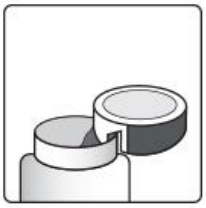
If you forget to take RINVOQ

- 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 tablet.

If you stop taking RINVOQ

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

How to open the bottle

	**Foil Cutting Tool** - on the cap of the bottle
	**1. How to puncture the foil** **1a.** Remove the cap from the bottle by pushing down and while still pushing, turn the cap anti-clockwise. **1b.** Turn the cap over and place the cutting tool near the edge of the foil seal.
	**2**. Push down to make a hole in the foil and move the cutting tool round the edge of the foil to continue cutting the foil.
	**3.** When you have taken your tablet, put the cap back on and close the bottle.

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

4. Possible side effects

RINVOQ can have side effects.

Not all side effects reported for RINVOQ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RINVOQ, please consult your healthcare provider for advice.

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)
- infection of the lung (pneumonia), which may cause shortness of breath, fever, and a cough with mucus
- infection in the blood (sepsis)
- allergic reaction (chest tightness, wheezing, swelling of the lips, tongue or throat, hives)

Other side effects

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

Frequent

- throat and nose infections
- cough
- acne

- 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)
- anaemia
- pain in your belly (abdomen)
- fatigue (feeling unusually tired and weak)
- headache
- hives (urticaria)
- urinary tract infection
- rash
- a spinning sensation (vertigo)
- dizziness
- infection of the lungs (bronchitis)
- swelling of the feet and hands (peripheral oedema)

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Less frequent

- thrush in the mouth (white patches in the mouth)
- increased levels of triglycerides (a type of fat in the blood) as shown in tests
- diverticulitis (painful inflammation of small pockets in the lining of your intestine)
- gastrointestinal perforation (a hole in the bowel)

Additional side effects in adolescents with atopic dermatitis

FREQUENT

- warts (skin papilloma)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

You can also report side effects to AbbVie (Pty) Ltd via this e-mail address: MEAPV@abbvie.com

5. How to store RINVOQ

Store all medicines out of reach of children.

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

Store RINVOQ at or below 25 °C

Store in original blister or bottle with the lid tightly closed 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

RINVOQ 30 mg prolonged-release tablets

- The active substance is upadacitinib. Each prolonged-release tablet contains 15 mg of upadacitinib (as upadacitinib hemihydrate).
- 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, iron oxide red (E172), iron oxide black (E172).

RINVOQ 30 mg prolonged-release tablets

- Each prolonged-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 prolonged-release tablets

- Each prolonged-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 15 mg prolonged-release tablets

RINVOQ 15 mg prolonged-release tablets are purple, oblong, biconvex tablets imprinted on one side with ‘a15’.

The tablets are provided in blisters or bottles.

The calendar blister packaging is composed of polyvinylchloride /polyethylene /polychlorotrifluoroethylene /aluminium

RINVOQ is available in packs containing 28 or 98 prolonged-release tablets and in multipacks of 84 comprising 3 cartons, each containing 28 prolonged-release tablets.

Each calendar blister contains 7 tablets.

The bottle is composed of high-density polyethylene (HDPE) with desiccant and a polypropylene cap.

RINVOQ is available in bottles with desiccant in a carton containing 30 prolonged-release tablets, each pack contains 1 bottle (30 tablet pack) or 3 bottles (90 tablet pack).

RINVOQ 30 mg prolonged-release tablets

RINVOQ 30 mg prolonged-release tablets are red, oblong, biconvex tablets imprinted on one side with ‘a30’.

The tablets are provided in blisters or bottles.

RINVOQ is available in packs containing 28 or 98 prolonged-release tablets.

Each calendar blister contains 7 tablets.

RINVOQ is available in bottles with desiccant containing 30 prolonged-release tablets, each pack contains 1 bottle (30 tablet pack) or 3 bottles (90 tablet pack).

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RINVOQ 45 mg prolonged-release tablets

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

The tablets are provided in blisters or bottles.

RINVOQ is available in packs containing 28 prolonged-release tablets.

Each calendar blister contains 7 tablets.

RINVOQ is available in bottles with desiccant containing 28 prolonged-release tablets, each pack contains 1 bottle.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

AbbVie (Pty) Ltd

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RINVOQ 15 mg: 54/3.1/0187

RINVOQ 30 mg: 57/3.1/0624

RINVOQ 45 mg: 57/3.1/0625

Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com

CCDS0520 v 17,18 & 19

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