

## Package leaflet: Information for the patient

### RINVOQ 15 mg prolonged-release tablets RINVOQ 30 mg prolonged-release tablets upadacitinib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

#### **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
- Ankylosing Spondylitis
- Atopic Dermatitis

##### 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.

#### 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, 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.

## **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)
- 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 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 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
- you have had diverticulitis (a type of inflammation of the large intestine) (see section 4)

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

- severe stomach pain especially accompanied by fever, nausea, and vomiting.

### **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 or ankylosing spondylitis. 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 diverticulitis 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) (see section 4).

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

### **Rinvoq with food and drink**

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.

## **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 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, as one tablet 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.

### **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.

### **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 tablet.

### **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)
- anaemia
- pain in your belly (abdomen)
- fatigue (feeling unusually tired and weak)
- headache
- hives (urticaria)

#### **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
- diverticulitis (painful inflammation of small pockets in the lining of your intestine)

## 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. You can also report side effects directly via

### United Kingdom

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## 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 and carton after 'EXP'.

This medicine does not require any special temperature storage conditions.

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 prolonged-release tablets

- Each prolonged-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 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).

### 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.

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.

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).

#### 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).

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

AbbVie Ltd.

M Maidenhead

SL6 4UB

UK

#### **Manufacturer**

AbbVie S.r.l.

S.R. 148 Pontina, km 52 SNC

04011 Campoverde di Aprilia (Latina)

Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

#### **United Kingdom**

AbbVie Ltd

Tel: +44 (0)1628 561090

**This leaflet was last revised in 10/2021**

#### **Other sources of information**

Detailed and updated information on this product is available by scanning the QR code included below or on the outer carton with a smart phone. The same information is also available on the following

URL: [www.rinvoq.eu](http://www.rinvoq.eu).



**To listen to or request a copy of this leaflet in Braille, large print or audio, please contact the local representative of the Marketing Authorisation Holder**