PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986 The medicine is dispensed with a doctor's prescription only

## RINVOQ® 15 mg RINVOQ® 30 mg RINVOQ® 45 mg

# The active ingredient and its quantity: Each RINVOQ 15 mg prolonged-release tablet contains 15 mg upadacitinib (as hemihydrate)

**Prolonged-release tablets** 

Contains 15 mg upadacitimin (as rieminydrate)
Each RINVOQ 30 mg prolonged-release tablet
contains 30 mg upadacitimib (as hemihydrate)
Each RINVOQ 45 mg prolonged-release tablet
contains 45 mg upadacitinib (as hemihydrate) Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

In addition to the leaflet, RINVOQ has a 'Patient Safety Information Card'. This card includes important safety information, which you should know before starting and during treatment with RINVOQ, and act accordingly. Read the 'Patient Safety Information Card' and the patient leafler starting treatment with the medicine Kart

before starting treatment with the medicine. Keep the card for further information if needed. 1. WHAT IS THE MEDICINE INTENDED FOR? RINVOQ is indicated for the treatment of:

 Moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). modifying anti-rheumatic drugs (DMARD RINVOQ may be used as monotherapy or combination with methotrexate. Active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. RINVOQ may be used as monotherapy or in combination with methotrexate. Active ankylosing spondylitis in adult patients who have responded inadequately to conventional

- Moderate to severe atopic dermatitis in adults and adolescents, aged 12 and older, who are candidates for systemic treatment.
- Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent. Adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.

Therapeutic group: selective immunosuppressants, Janus kinase inhibitors. RINVOQ works by reducing the activity of an enzyme called Janus kinase' in the body, which lowers inflammation.

RINVOQ is used to treat adults with rheumatoid

arthritis. Rheumatoid arthritis is a disease that causes

Rheumatoid arthritis

**Psoriatic arthritis** 

Ankylosing spondylitis

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 dermatitis, also known as atopic eczema. HINVOQ 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 fatique.

and reduce fatigue. Crohn's disease

**Ulcerative** colitis

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 adults with Cronn'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. BEFORE USING THE MEDICINE Do not use the medicine if: you are sensitive (allergic) to upadacitinib or any of the other ingredients contained in the medicine (listed in section 6)

you have a severe infection (such as pneumonia or bacterial skin infection) you have active tuberculosis (TB)

you are pregnant (see section "Pregnancy, breast-feeding and fertility")

Special warnings regarding use of the medicin Before beginning and during treatment with RINVOQ, tell the doctor if:

you have severe liver problems

# RINVOQ, tell the doctor if: you have an infection or if you often get infections. Tell your doctor if you get symptoms such as fever, wounds, feeling more tired than usual or dental problems as these can be signs of infection. RINVOQ can reduce your body's ability to fight infections and may make an existing infection worse or increase the chance of you getting 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

appropriate for you.

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. not recommended while using HINVOQ. 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

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.

your liver does not work as well as it should

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

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

non-steroidal anti-inflammatory medicines.

ell 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. Tests and follow-up
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 enzymes. The tests are to check to RINVOQ is not causing problems. There is a higher rate of infection in patients 65 years of age an 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 years of age with rheumatoid arthritis,

psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, or Crohn's disease. This is because it has not been studied in this age group.

- **Drug interactions** If you are taking, or have recently taken, other
- medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because some medicines may reduce how well RINVOQ works or may increase the
- risk of getting side effects.
- · 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 condition

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 upadacitinib.

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 fertility 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 you are a woman of child-bearing potential, you

straight away. If your daughter has her first menstrual period while taking RINVOQ, you should inform the doctor. **Driving and using machines** 

Do not drive or use machines if you experience dizziness or a spinning sensation (vertigo) when taking RINVOQ until they resolve.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis The recommended dosage is generally 15 mg, once

a day. Atopic dermatitis Adults:

Elderly: If you are 65 years of age or older, the recommended dosage is generally 15 mg once a day.

## a day.

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 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:

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

Elderly:

treatment.

Your doctor may reduce your dose if you have kidney problems, or you are prescribed certain other medicines Do not exceed the recommended dose Method of administration

## 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 accidentally take a higher dosage, contact your doctor. You may get some of the side effects

your doctor. You n listed in section 4.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. If you forget to take the medicine 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

you to stop taking it. Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them. If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

not stop taking RINVOQ unless your doctor tells

throat and nose infections

· non-melanoma skin cancer

Serious side effects

in 100 users

acne

in 100 users

hives (urticaria) urinary tract infection

cough

Talk to your doctor if you notice any of the following side effects: Very common side effects – effects that occur in more than 1 user in 10

Common side effects - effects that occur in 1-10

- inflammation (swelling) of the hair follicles anaemia abdominal pain fatigue (feeling unusually tired and weak) headache
- Reporting of side effects
  - 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. FURTHER INFORMATION

Film-coating:

- Film coating:
- The tablets are provided in blisters 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.

Each calendar blister contains 7 tablets. 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 15 mg prolonged-release tablets

The recommended dosage is generally 15 mg or 30 mg, once a day, as prescribed by your doctor. Your doctor may decide to increase or decrease your dosage, depending on how the medicine is working

Adolescents (ages 12-17) weighing at least 30 kg:

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

- usual the following day
- 4. SIDE EFFECTS As with any medicine, use of RINVOQ may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
- that occur in 1-10 in 1,000 users allergic reaction (chest tightness, wheezing, swelling of the lips, tongue or throat, hives) uncommon effects that occur in 1-10 in 1,000 users Other side effects
  - increased levels of liver enzymes, shown in blood tests (sign of liver problems) weight gain
- 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) If a side effect has occurred, if any of the side effects worsen or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.
- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor Do not use the medicine after the expiry date (exp. date) that appears on the outer package and blister. The expiry date refers to the last day of that month. month Rinvoq 15 mg, Rinvoq 30 mg Store up to 30°C
  - polyvinyl alcohol, macrogol/polyethylene glycol, talc, titanium dioxide (E171), black iron oxide (E172) / ferrosoferric oxide, iron oxide red (E172)
- RINVOQ 15 mg prolonged-release tablets RINVOQ 15 mg prolonged-release tablets are purple, oblong, biconvex tablets imprinted on one side with

polyvinyl alcohol, macrogol/polyethylene glycol, titanium dioxide (E171), talc, iron oxide yellow (E172), iron oxide red (E172).

What the medicine looks like and contents of

License holder and its address:

RINVOQ 45 mg prolonged-release tablets

RIN APL SEP24 CL P3

RINVOQ 30 mg prolonged-release tablets Core tablet: microcrystalline cellulose, mannitol, hypromellose, tartaric acid (powdered), magnesium stearate, silica colloidal anhydrous/colloidal silicon dioxide Film-coating: polyvinyl alcohol, macrogol/polyethylene glycol, talc, titanium dioxide (E171), iron oxide red (E172)

RINVOQ is available in packs containing 28 prolonged-release tablets. Each calendar blister contains 7 tablets. Not all pack sizes may be marketed.

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172-42-37344

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

# Always use the preparation according to the doctor's instructions.

## in your body.

# The recommended dosage is generally 15 mg once

## 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.

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

# 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 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 take a double dose to make up for a forgotten tablet Adhere to the treatment as recommended by the doctor. If you stop taking the medicine
  - infection such as shingles or painful skin rash with blisters (herpes zoster) – common side effects – effects that occur in 1-10 in 100 users infection of the lung (pneumonia), which may cause shortness of breath, fever, and a cough with mucus – common side effects – effects that occur in 1-10

infection in the blood (sepsis) - uncommon - effects

Talk to your doctor or get medical help straight away if you get any signs of:

- 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
- infection of the lungs (bronchitis) Uncommon side effects – effects that occur in 1-10 in 1,000 users
- Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/ 5. HOW SHOULD THE MEDICINE BE STORED?
  - Rinvoq 45 mg No special storage requirements. It is recommended to store at room temperature. Store in the original blister in order to protect from
- RINVOQ 45 mg prolonged-release tablets Core tablet: microcrystalline cellulose, mannitol, hypromellose, tartaric acid (powdered), magnesium stearate, silica colloidal anhydrous/ colloidal silicon dioxide
- a30' The tablets are provided in blisters in packs containing 28 or 98 prolonged-release tablets.

 Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Manufacturer name and its address: AbbVie Deutschland GmbH & Co. KG, Knollstrasse 67061, Ludwigshafen, Germany

AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel

164-29-36194 RINVOQ 30 mg prolonged-release tablets 168-69-37036

a spinning sensation (vertigo) dizziness

### What RINVOQ contains In addition to the active ingredient, the medicine also contains: RINVOQ 15 mg prolonged-release tablets Core tablet: microcrystalline cellulose, mannitol, hypromellose, tartaric acid (powdered), magnesium stearate, silica colloidal anhydrous/colloidal silicon dioxide