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
RINVOQ® LQ

The active ingredient and its quantity:
Each RINVOQ 15 MG prolonged-release tablet contains 15 mg upadacitinib (as hemihydrate)
Each RINVOQ 30 MG prolonged-release tablet contains 30 mg upadacitinib (as hemihydrate)
Each RINVOQ 45 MG prolonged-release tablet contains 45 mg upadacitinib (as hemihydrate)
Each RINVOQ LQ 1 ml of oral solution contains 1mg of upadacitinib (as hemihydrate)
Inactive and allergenic ingredients in the preparation – see section 6 "Further Information" and section 2 "Important information about some of the medicine's ingredients" in this leaflet.

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 leaflet before starting treatment with the preparation. Keep the card for further information if needed.

1. WHAT IS THE MEDICINE INTENDED FOR?

- RINVOQ 15 MG 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). RINVOQ may be used as monotherapy or in combination with methotrexate.
- RINVOQ 15 MG is indicated for the treatment of 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.
- Axial spondyloarthritis
  - RINVOQ 15 MG is indicated for the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA) in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).
  - RINVOQ 15 MG is indicated for the treatment of active ankylosing spondylitis ([AS]; Radiographic Axial Spondyloarthritis) in adult patients who have responded inadequately to conventional therapy.
- RINVOQ 15 MG/RINVOQ 30 MG is indicated for the treatment of moderate to severe atopic dermatitis in adults and adolescents aged 12 and older who are candidates for systemic treatment.
- RINVOQ 15 MG/RINVOQ 30 MG/RINVOQ 45 MG is indicated for the treatment of 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.
- RINVOQ 15 MG/RINVOQ 30 MG/RINVOQ 45 MG is indicated for the treatment of 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.
- RINVOQ 15 MG/RINVOQ LQ is indicated for the treatment of patients 2 years of age and older with active juvenile psoriatic arthritis (JPsA) who have had an inadequate response or intolerance to one or more TNF blockers.
  RINVOQ 15 MG/RINVOQ LQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.
- RINVOQ 15 MG/RINVOQ LQ is indicated for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers.
  RINVOQ 15 MG /RINVOQ LQ is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.

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.

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.

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.

Juvenile psoriatic arthritis (JPsA)
RINVOQ is used to treat patients 2 years of age and older with juvenile psoriatic arthritis. Juvenile psoriatic arthritis is a disease that causes inflamed joints and psoriasis.
RINVOQ is expected to help reduce pain, stiffness, and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash, tiredness, and help to slow damage to the bone and cartilage in your joints. These effects can help you to do normal daily activities and so improve your health-related quality of life.

Polyarticular juvenile idiopathic arthritis (pJIA)
RINVOQ is used to treat patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. Polyarticular juvenile idiopathic arthritis is a disease that causes inflamed joints.
RINVOQ is expected to help reduce pain, stiffness and swelling in your joints, tiredness, and help to slow damage to the bone and cartilage in your joints. These effects can help you to do normal daily activities and so improve your health-related quality of life.

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 have severe liver problems
- you are pregnant (see section "Pregnancy, breast-feeding and fertility" below)

Special warnings regarding use of the medicine
Before beginning and during treatment with 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 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.
- 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, redness or discolouration in the leg or arm as these can be signs of blood clots in the veins.
- you experience sudden changes to your eyesight. You should seek medical advice straight away if you have sudden symptoms such as blurry vision, partial or complete loss of vision, as these may be a sign of blocked blood flow in the eyes.
- 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.
- you repeatedly see a tablet or tablet pieces in your stool.

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.

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 RINVOQ is not causing problems.

Elderly
There is a higher rate of infection in patients 65 years of age 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 tablets are 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.
The safety and efficacy of RINVOQ LQ in children with atopic dermatitis have not been established.
RINVOQ tablets are not recommended for use in children and adolescents under 18 years of age with 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.
The safety and efficacy of RINVOQ 15 MG/RINVOQ LQ in paediatric patients less than 2 years of age with polyarticular juvenile idiopathic arthritis (pJIA) or juvenile psoriatic arthritis (JPsA) have not been established.

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 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 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
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 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.

Important information about some of the medicine's ingredients
Rinvoq LQ contains sodium benzoate. This medicine contains 0.3 mg sodium benzoate in each 1 mL of oral solution.
Rinvoq LQ contains sodium. This medicine contains less than 1 mmol (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
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 axial spondyloarthritis (non-radiographic axial spondyloarthritis and ankylosing spondylitis)
The recommended dosage is generally 15 mg, once a day.

Atopic dermatitis
Adults:
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 in your body.
Elderly:
If you are 65 years of age or older, the recommended dosage is generally 15 mg once a day.
Adolescents (ages 12-17) weighing at least 30 kg:
The recommended dosage is generally 15 mg once 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:
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.

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.

Juvenile psoriatic arthritis or polyarticular juvenile idiopathic arthritis
The recommended dosage for patients 2 years of age and older is based on body weight.
- Patient weight of 10 kg to less than 20 kg:
  RINVOQ LQ 3 mg (3 mL oral solution) twice daily.
  RINVOQ 15 MG (tablets) is not recommended.
- Patient weight of 20 kg to less than 30 kg:
  RINVOQ LQ 4 mg (4 mL oral solution) twice daily.
  RINVOQ 15 MG (tablets) is not recommended.
- Patient weight of 30 kg and greater:
  RINVOQ LQ 6 mg (6 mL oral solution) twice daily.
  RINVOQ 15 MG (one 15 mg tablet) once daily.

Do not exceed the recommended dose

Method of administration
- Swallow RINVOQ tablets 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.
- Take RINVOQ tablets once daily.
- Take RINVOQ LQ twice daily.
- RINVOQ tablets/RINVOQ LQ oral solution can be taken with or without food.
- 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.
- RINVOQ LQ is not the same as RINVOQ tablets. Do not switch between RINVOQ LQ and RINVOQ tablets unless the change has been made by your doctor.

Read section 7 'Instructions for use' at the end of this leaflet before you give a dose of RINVOQ LQ.

If you accidentally took a higher dosage, contact your doctor. You may get some of the side effects listed in section 4.
If you or your child 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 forgot to take the medicine
- 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 the recommended dose as usual the following day.
- Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

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

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

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.

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 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 in 100 users
- infection in the blood (sepsis) - uncommon - effects 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
Talk to your doctor if you notice any of the following side effects:
Very common side effects – effects that occur in more than 1 in 10 users
- throat and nose infections
- acne

Common side effects – effects that occur in 1-10 out of 100 users
- 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 in blood tests (sign of liver problems)
- weight gain
- inflammation (swelling) of the hair follicles
- flu
- anaemia
- abdominal pain
- 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)

Uncommon side effects – effects that occur in 1-10 out of 1,000 users
- 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
Common side effects – effects that occur in 1-10 out of 100 users
- warts (skin papilloma)

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.

Reporting of side effects
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?

- 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.
- For RINVOQ 15 MG, RINVOQ 30 MG:
  Store up to 30°C.
- For 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 moisture.
- For RINVOQ LQ:
  Store below 30°C. Can be refrigerated (2°C to 8°C). Do not freeze. Store the bottle upright in a carton, in a cool dark place.
  Discard remaining oral solution 60 days after opening the bottle.
- 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

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
- Film coating:
  Polyvinyl alcohol, macrogol/polyethylene glycol, talc, titanium dioxide (E171), black iron oxide (E172)/ferrosoferric oxide, iron oxide red (E172)

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 45 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 yellow (E172), iron oxide red (E172)

RINVOQ LQ oral solution
Sucralose, citric acid anhydrous, sodium citrate dihydrate, sodium benzoate (E211), purified water

What the medicine 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 in packs containing 28 or 98 prolonged-release tablets and in multipacks of 84 tablets comprising 3 cartons, each containing 28 prolonged-release tablets.
Each calendar blister contains 7 tablets.
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 in packs containing 28 or 98 prolonged-release 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 in packs containing 28 prolonged-release tablets.
Each calendar blister contains 7 tablets.
RINVOQ LQ oral solution
Rinvoq LQ oral solution is a clear, colorless to light yellow solution.
The solution is supplied in a bottle containing 180 ml of solution in a carton box. In addition to the bottle, the cardboard box also contains a reusable syringe and adapter.

Not all pack sizes may be marketed.
- **License holder and its address:**
  AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel
- **Manufacturer name and its address:**
  - **RINVOQ 15 MG/30 MG/45 MG TABLETS:**
    AbbVie Deutschland GmbH & Co. KG, Knollstrasse 67061, Ludwigshafen, Germany
  - **RINVOQ LQ ORAL SOLUTION:**
    AbbVie Inc., North Chicago, IL 60064, USA
- Revised in October 2025
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:**
  RINVOQ 15 MG 164-29-36194
  RINVOQ 30 MG 168-69-37036
  RINVOQ 45 MG 172-42-37344
  RINVOQ LQ 179-64-38152

7. INSTRUCTIONS FOR USE

This Instructions for Use contains information on how to prepare and give a dose of RINVOQ LQ oral solution.
Read this Instructions for Use before you give RINVOQ LQ to your child, and each time you get a new bottle. There may be new information. This information does not take the place of talking to your doctor about your child's medical condition or treatment.

Important Information You Need to Know Before Giving RINVOQ LQ

⚠ Keep the bottle and supplies out of sight and reach of children.
⚠ Only use the syringe provided. **Do not** share the syringe with other people or use it with other medicines.
⚠ Contact your doctor if your child takes too much oral solution or does not receive the full dose.
- Use RINVOQ LQ within 60 days of opening the bottle. To help you remember, write the date you opened the bottle on the carton.
- **Do not** open a new bottle of RINVOQ LQ until you have finished the previous bottle. Use a new syringe when you open a new bottle.
- RINVOQ LQ oral solution is clear and colorless to light yellow in color.
- Keep these instructions and the carton your RINVOQ LQ oral solution and supplies came in for future use.

Supplies in Each Carton

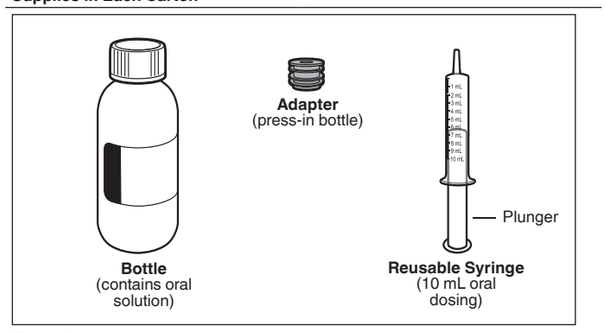

Figure A

Disposal of RINVOQ LQ

⚠ Dispose of (throw away) the syringe and the bottle when you have finished the bottle or 60 days after opening.
- Ask your pharmacist how to properly dispose of (throw away) any unused medicine.
- Rinse syringe then place in household trash.

Preparing RINVOQ LQ

1. **Check the prescribed dose.**
   a. Check your child's prescribed dose in milliliters (mL) and find this mL marking on the syringe.
   b. Only use the syringe provided to give the prescribed dose.
2. **Check expiration date.**
   a. Check the bottle and make sure the expiration date has not passed (see **Figure B**).
   ⚠ **Do not** use RINVOQ LQ after the expiration date printed on the carton and the bottle after "EXP".

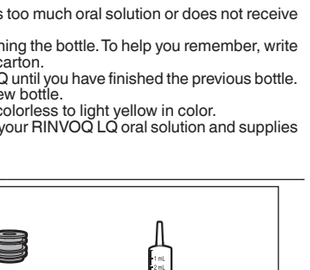

Figure B

3. **Check supplies.**
   a. Check the supplies and make sure they are not damaged (see **Figure C**).
   b. **Only use the syringe if it is clean and dry.**
   c. Make sure that the plunger is all the way in the syringe.
   ⚠ **Do not** use the supplies if they are wet, damaged, or appear to be tampered with.

Figure C

4. **Open the bottle.**
   a. Press down and twist the cap to remove it from the bottle (see **Figure D**). **Do not** throw away the cap.

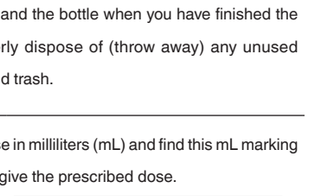

Figure D

5. **Insert the adapter (first time only).**
   a. While holding the bottle firmly, use your thumb to push the adapter all the way down to the rim of the bottle (see **Figure E**).
   Note: You may need to apply pressure to the adapter.
   ⚠ **Do not** remove adapter after it is inserted.

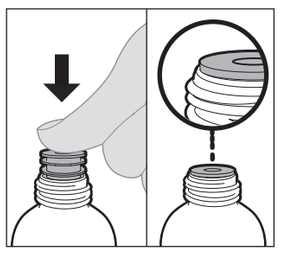

Figure E

Measuring the Dose

6. **Insert the syringe into the bottle then turn it upside down.**
   a. Insert the tip of the syringe into the adapter.
   b. With the syringe attached to the bottle, turn the bottle upside down (see **Figure F**).

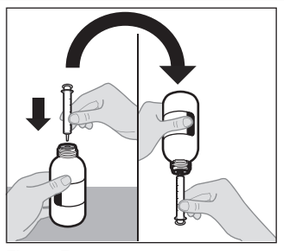

Figure F

7. **Draw the oral solution into the syringe.**
   a. Slowly pull the plunger down (see **Figure G**).
   b. Check the syringe for air bubbles.
   Note: You may feel pressure when pulling the plunger.

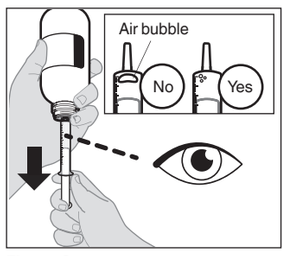

Figure G

8. **Remove large air bubbles (see Figure H).**
   a. While holding the bottle, flick the sides of the syringe to send large air bubbles to the tip.
   b. With the syringe attached to the bottle, move the plunger up and down to return air bubbles back into the bottle.
   c. Repeat **Step 8** until any large air bubbles are gone.
   Note: Small air bubbles are normal.

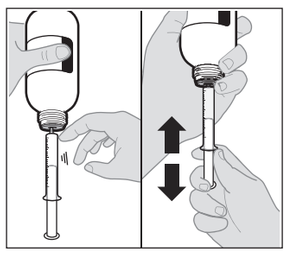

Figure H

9. **Measure the dose.**
   a. After any large air bubbles are removed, move the plunger until it is even with the marking of the dose on the syringe (see **Figure I**).

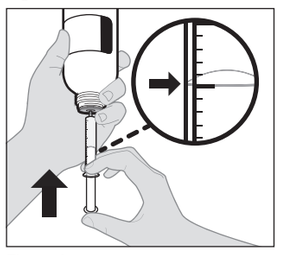

Figure I

10. **Turn the bottle upright, and then remove the syringe.**
    a. With the syringe attached to the bottle, turn the bottle upright.
    b. Hold the middle of the syringe and carefully remove it from the bottle (see **Figure J**).
    ⚠ **Do not** touch the plunger to avoid oral solution accidentally coming out of the syringe before you are ready to give the medicine.

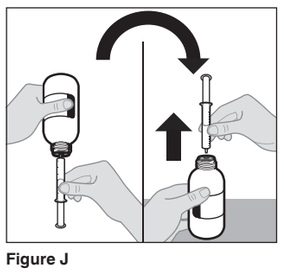

Figure J

Giving RINVOQ LQ

11. **Check the dose.**
    a. Check that the syringe has the correct dose of oral solution (see **Figure K**).
    b. Check the syringe for large air bubbles.
    c. If the dose is not correct or you see large air bubbles, return to **Step 6.**

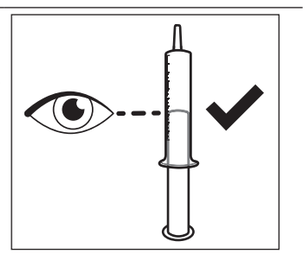

Figure K

12. **Give the oral solution.**
    a. Place the syringe against the inside of the child's cheek.
    b. Push the plunger to give the entire dose into the child's mouth (see **Figure L**).
    c. Give the child a drink of water.
    Note: Oral solution must be given within 1 hour of filling the syringe.

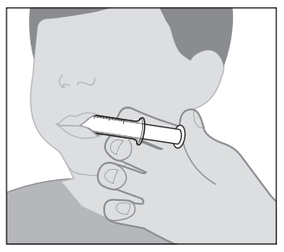

Figure L

Storing RINVOQ LQ

13. **Close and store the bottle.**
    a. With the adapter still inserted in the bottle, screw the cap back on to the bottle to seal it (see **Figure M**).
    b. Store the bottle upright in the carton between uses.
    c. Store the bottle upright in the carton below 30°C in a cool, dark place. Can be refrigerated (2°C to 8°C). Do not freeze.
    d. Keep the bottle, supplies, and all medicines out of the sight and reach of children.

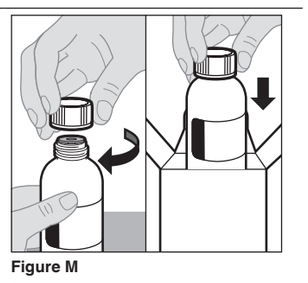

Figure M

14. **Rinse and store the syringe.**
    a. Remove the plunger from the syringe then rinse both parts with water (see **Figure N**).
    ⚠ **Do not** use soap or put the syringe in the dishwasher to clean it.
    b. Allow separated parts to air dry on a clean surface.
    c. Store the syringe in a clean, dry place.

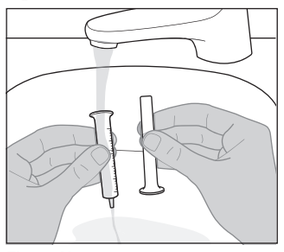

Figure N

When you have finished the bottle, see "Disposal of RINVOQ LQ."