MEDICATION GUIDE

RINVOQ® (RIN-VOKE)
(upadacitinib)
extended-release tablets, for oral use

RINVOQ® LQ (RIN-VOKE EL-CUE)
(upadacitinib)
oral solution

What is the most important information I should know about RINVOQ/RINVOQ LQ?

RINVOQ/RINVOQ LQ can cause serious side effects, including:

1. Serious Infections.

RINVOQ/RINVOQ LQ is a medicine that affects your immune system. RINVOQ/RINVOQ LQ can lower the ability of your immune system to fight infections. Some people have had serious infections while taking RINVOQ, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

- Your healthcare provider should test you for TB before starting treatment with RINVOQ/RINVOQ LQ.
- Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with RINVOQ/RINVOQ LQ.
- You should not start taking RINVOQ/RINVOQ LQ if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster).
- **Before starting RINVOQ/RINVOQ LQ, tell your healthcare provider if you**:
  - are being treated for an infection.
  - have had an infection that does not go away or that keeps coming back.
  - have diabetes, chronic lung disease, HIV, or a weak immune system.
  - have TB or have been in close contact with someone with TB.
  - have had shingles (herpes zoster).
  - have or have had hepatitis B or C.
  - live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or become more severe if you use RINVOQ/RINVOQ LQ. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
  - think you have an infection or have symptoms of an infection such as:
    - fever, sweating, or chills
    - shortness of breath
    - warm, red, or painful skin or sores on your body
    - muscle aches
    - feeling tired
    - blood in your phlegm
    - diarrhea or stomach pain
    - cough
    - weight loss
    - burning when you urinate or urinating more often than usual

After starting RINVOQ/RINVOQ LQ, call your healthcare provider right away if you have any symptoms of an infection. RINVOQ/RINVOQ LQ can make you more likely to get infections or make worse any infections that you have. If you get a serious infection, your healthcare provider may stop your treatment with RINVOQ/RINVOQ LQ until your infection is controlled.

2. Increased risk of death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors. RINVOQ/RINVOQ LQ is a JAK inhibitor medicine.

3. Cancer and immune system problems.

RINVOQ/RINVOQ LQ may increase your risk of certain cancers by changing the way your immune system works. Lymphoma and other cancers, including skin cancers can happen in people taking RINVOQ/RINVOQ LQ. People taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors have a higher risk of certain cancers including lymphoma and lung cancer, especially if you are a current or past smoker.

Tell your healthcare provider if you have ever had any type of cancer. Follow your healthcare provider's advice about having your skin checked for skin cancer during treatment with RINVOQ/RINVOQ LQ. Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor (SPF 30 and above). This is especially important if your skin is very fair or if you have a family history of skin cancer.

4. Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and taking a medicine in the class of medicines called JAK inhibitors, especially if you are a current or past smoker.

Get emergency help right away if you have any symptoms of a heart attack or stroke while taking RINVOQ/RINVOQ LQ, including:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort

- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded
- weakness in one part or on one side of your body
- slurred speech

5. Blood Clots (thromboses).
Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) and arteries (arterial thrombosis) can happen in some people taking RINVOQ/RINVOQ LQ. This may be life-threatening and cause death. Blood clots in the veins of the legs (DVT) and lungs (PE) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors.

- Tell your healthcare provider if you have had blood clots in the veins of your legs or lungs in the past.
- Get medical help right away if you have signs and symptoms of blood clots during treatment with RINVOQ/RINVOQ LQ, including:
  - swelling
  - pain or tenderness in one or both legs
  - sudden unexplained chest or upper back pain
  - shortness of breath or difficulty breathing

6. Allergic reactions. Symptoms such as rash (hives), trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat, that may mean you are having an allergic reaction have been seen in people taking RINVOQ. Some of these reactions were serious. If any of these symptoms occur during treatment with RINVOQ/RINVOQ LQ, stop taking RINVOQ/RINVOQ LQ and get emergency medical help right away.

7. Tears (perforation) in the stomach or intestines.

- Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking RINVOQ/RINVOQ LQ can get tears in their stomach or intestines. This happens most often in people who take nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids.
- Get medical help right away if you get stomach-area pain, fever, chills, nausea, or vomiting.

8. Low blood sugar (hypoglycemia) in people with diabetes. If you have diabetes, your healthcare provider may tell you to check your blood sugar (glucose) more often during treatment with RINVOQ/RINVOQ LQ. Call your healthcare provider if you have any problems with low blood sugar.

9. Changes in certain laboratory test results.
Your healthcare provider should do blood tests before you start taking RINVOQ/RINVOQ LQ and while you take RINVOQ/RINVOQ LQ to check for the following:

- **low neutrophil and lymphocyte counts.** Neutrophils and lymphocytes are types of white blood cells that help the body fight off infections.
- **low red blood cell counts.** Red blood cells carry oxygen. Low red blood cells means you may have anemia, which may make you feel weak and tired.
- **increased cholesterol levels.** Your healthcare provider should do blood tests to check your cholesterol levels approximately 12 weeks after you start taking RINVOQ/RINVOQ LQ, and as needed.
- **elevated liver enzymes.** Liver enzymes help to tell if your liver is functioning normally. Elevated liver enzymes may indicate that your healthcare provider needs to do additional tests on your liver.

You should not take RINVOQ/RINVOQ LQ if your neutrophil count, lymphocyte count, or red blood cell count is too low or your liver tests are too high. Your healthcare provider may stop your RINVOQ/RINVOQ LQ treatment for a period of time if needed because of changes in these blood test results.

See **"What are the possible side effects of RINVOQ/RINVOQ LQ?"** for more information about side effects.

What is RINVOQ/RINVOQ LQ?
RINVOQ/RINVOQ LQ is a prescription medicine that is a Janus kinase (JAK) inhibitor.

- RINVOQ is used to treat adults with moderate to severe rheumatoid arthritis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well or could not be tolerated.
- RINVOQ is used to treat adults with active psoriatic arthritis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well or could not be tolerated.

- RINVOQ is used to treat adults and children 12 years of age and older with moderate to severe eczema (atopic dermatitis) that did not respond to previous treatment and their eczema is not well controlled with other pills or injections, including biologic medicines, or the use of other pills or injections is not recommended.
- RINVOQ is used to treat adults with moderate to severe ulcerative colitis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used and did not work well or could not be tolerated, or after taking a different injection or pill (systemic therapy) when your healthcare provider does not recommend TNF blockers.
- RINVOQ is used to treat adults with moderate to severe Crohn's disease when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used and did not work well or could not be tolerated, or after taking a different injection or pill (systemic therapy) when your healthcare provider does not recommend TNF blockers.
- RINVOQ is used to treat adults with active ankylosing spondylitis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well or could not be tolerated.
- RINVOQ is used to treat adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation when a tumor necrosis factor (TNF) blocker medicine has been used, and did not work well or could not be tolerated.
- RINVOQ/RINVOQ LQ is used to treat children 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well or could not be tolerated.
- RINVOQ/RINVOQ LQ is used to treat children 2 to less than 18 years of age with active psoriatic arthritis when 1 or more medicines called tumor necrosis factor (TNF) blockers have been used, and did not work well or could not be tolerated.
- RINVOQ is used to treat adults with giant cell arteritis.

It is not known if RINVOQ/RINVOQ LQ is safe and effective in children with ankylosing spondylitis, non-radiographic axial spondyloarthritis, ulcerative colitis, or Crohn's disease.

It is not known if RINVOQ is safe and effective in children under 12 years of age with atopic dermatitis.

It is not known if RINVOQ LQ is safe and effective in children with atopic dermatitis.

It is not known if RINVOQ/RINVOQ LQ is safe and effective in children under 2 years of age with pJIA or psoriatic arthritis.

Do not take RINVOQ/RINVOQ LQ if you are allergic to upadacitinib or any of the ingredients in RINVOQ/RINVOQ LQ. See the end of this Medication Guide for a complete list of ingredients in RINVOQ/RINVOQ LQ.

Before taking RINVOQ/RINVOQ LQ, tell your healthcare provider about all of your medical conditions, including if you:

- See **"What is the most important information I should know about RINVOQ/RINVOQ LQ?"**
- have an infection.
- are a current or past smoker.
- have had a heart attack, other heart problems, or stroke.
- have liver problems.
- have kidney problems.
- have unexplained stomach (abdominal) pain, have a history of diverticulitis or ulcers in your stomach or intestines, or are taking NSAIDs.
- have diabetes.
- have low red or white blood cell counts.
- have recently received or are scheduled to receive an immunization (vaccine). People who take RINVOQ/RINVOQ LQ should not receive live vaccines.
- are pregnant or plan to become pregnant. Based on animal studies, RINVOQ/RINVOQ LQ may harm your unborn baby.

  Females who are able to become pregnant:
  - Your healthcare provider will check whether or not you are pregnant before you start treatment with RINVOQ/RINVOQ LQ.
  - You should use effective birth control (contraception) to avoid becoming pregnant during treatment with RINVOQ/RINVOQ LQ and for 4 weeks after your last dose of RINVOQ/RINVOQ LQ.
  - Tell your healthcare provider if you think you are pregnant or become pregnant during treatment with RINVOQ/RINVOQ LQ.
  - There is a pregnancy surveillance program for RINVOQ/RINVOQ LQ. The purpose of the program is to collect information about the health of you and your baby. If you become pregnant while taking RINVOQ/RINVOQ LQ, you are encouraged to report the pregnancy by calling 1-800-633-9110.

- are breastfeeding or plan to breastfeed. RINVOQ/RINVOQ LQ may pass into your breast milk. You and your healthcare provider should decide if you will take RINVOQ/RINVOQ LQ or breastfeed. **Do not** breastfeed during treatment with RINVOQ/RINVOQ LQ and for 6 days after your last dose of RINVOQ/RINVOQ LQ.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RINVOQ/RINVOQ LQ and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- medicines for fungal infections (such as ketoconazole, itraconazole, posaconazole or voriconazole) or clarithromycin (for bacterial infections) as these medicines may increase the amount of RINVOQ/RINVOQ LQ in your blood.
- rifampicin (for bacterial infections) or phenytoin (for neurological disorders) as these medicines may decrease the effect of RINVOQ/RINVOQ LQ.
- medicines that affect your immune system (such as azathioprine and cyclosporine) as these medicines may increase your risk of infection.

Ask your healthcare provider or pharmacist, if you are not sure if you are taking any of these medicines.
Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take RINVOQ/RINVOQ LQ?

- Take RINVOQ/RINVOQ LQ exactly as your healthcare provider tells you to use it.
- Take RINVOQ LQ 2 times a day with or without food.
- Take RINVOQ tablets 1 time a day with or without food.
- Swallow RINVOQ tablets whole. Do not split, crush, or chew the tablets.
- 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 healthcare provider.
- If you take too much RINVOQ/RINVOQ LQ, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What should I avoid while taking RINVOQ/RINVOQ LQ?

Avoid food or drink containing grapefruit during treatment with RINVOQ/RINVOQ LQ. Eating grapefruit or drinking grapefruit juice may increase the risk of side effects.

What are the possible side effects of RINVOQ/RINVOQ LQ?

RINVOQ/RINVOQ LQ may cause serious side effects, including:

- See **"What is the most important information I should know about RINVOQ/RINVOQ LQ?"**

The most common side effects of RINVOQ/RINVOQ LQ in people treated for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and polyarticular juvenile idiopathic arthritis include:

- upper respiratory tract infections (common cold, sinus infections)
- shingles (herpes zoster)
- herpes simplex virus infections, including cold sores
- bronchitis
- nausea
- cough
- fever
- acne
- headache

The most common side effects of RINVOQ in people treated for giant cell arteritis include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- tiredness
- swelling of the feet and hands (peripheral edema)
- cough
- low red blood cell count (anemia)
- rash
- shingles (herpes zoster)
- nausea

The most common side effects of RINVOQ in people treated for atopic dermatitis include:

- upper respiratory tract infections (common cold, sinus infections)
- acne
- herpes simplex virus infections, including cold sores
- headache
- stomach-area (abdominal) pain
- fever
- increased weight
- shingles (herpes zoster)
- flu

- increased blood levels of creatine phosphokinase
- cough
- allergic reactions
- inflammation of hair follicles
- nausea
- tiredness
- low white blood cell count (neutropenia)
- muscle pain
- flu-like illness

The most common side effects of RINVOQ in people treated for ulcerative colitis include:

- upper respiratory tract infections (common cold, sinus infections)
- acne
- herpes simplex virus infections, including cold sores
- inflammation of the hair follicles
- rash
- flu
- shingles (herpes zoster)
- increased blood cholesterol levels
- increased blood levels of creatine phosphokinase
- increased liver enzyme levels
- low number of certain types of white blood cells (neutropenia, lymphopenia)
- fever

The most common side effects of RINVOQ in people treated for Crohn's disease include:

- upper respiratory tract infections (common cold, sinus infections)
- bronchitis
- pneumonia
- flu
- acne
- herpes simplex virus infections, including cold sores
- tiredness
- cough
- fever
- shingles (herpes zoster)
- headache
- increased blood levels of creatine phosphokinase
- increased liver enzyme levels
- low number of red blood cells (anemia)
- low number of white blood cells (neutropenia, leukopenia)
- infection of the stomach and intestine (gastroenteritis)

Separation or tear to the lining of the back part of the eye (retinal detachment) has happened in people with atopic dermatitis treated with RINVOQ. Call your healthcare provider right away if you have any sudden changes in your vision during treatment with RINVOQ/RINVOQ LQ.

Some people taking RINVOQ may see medicine residue (a whole tablet or tablet pieces) in their stool. If this happens, call your healthcare provider.

These are not all the possible side effects of RINVOQ/RINVOQ LQ.
Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store RINVOQ/RINVOQ LQ?

- Store RINVOQ tablets between 36°F to 77°F (2°C to 25°C).
- Store RINVOQ tablets in the original bottle to protect from moisture.
- Store RINVOQ LQ between 36°F to 86°F (2°C to 30°C).
- Throw away (discard) remaining RINVOQ LQ 60 days after opening the bottle.
- **Keep RINVOQ/RINVOQ LQ and all medicines out of the reach of children.**

General information about the safe and effective use of RINVOQ/RINVOQ LQ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RINVOQ/RINVOQ LQ for a condition for which it was not prescribed. Do not give RINVOQ/RINVOQ LQ to other people, even if they have the same symptoms that you have. It may harm them.
You can ask your pharmacist or healthcare provider for information about RINVOQ/RINVOQ LQ that is written for health professionals.

What are the ingredients in RINVOQ 15 mg tablets?

Active ingredient: upadacitinib
Inactive ingredients: colloidal silicon dioxide, ferrosoferric oxide, hypromellose, iron oxide red, magnesium stearate, mannitol, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, talc, tartaric acid and titanium dioxide.

What are the ingredients in RINVOQ 30 mg tablets?
Active ingredient: upadacitinib
Inactive ingredients: colloidal silicon dioxide, hypromellose, iron oxide red, magnesium stearate, mannitol, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, talc, tartaric acid and titanium dioxide.
What are the ingredients in RINVOQ 45 mg tablets?
Active ingredient: upadacitinib
Inactive ingredients: colloidal silicon dioxide, hypromellose, iron oxide yellow and iron oxide red, magnesium stearate, mannitol, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, talc, tartaric acid and titanium dioxide.
What are the ingredients in RINVOQ LQ?
Active ingredient: upadacitinib
Inactive ingredients: citric acid anhydrous, purified water, sodium benzoate, sodium citrate dihydrate and sucralose.
Manufactured by: AbbVie Inc., North Chicago, IL 60064, USA
RINVOQ® is a registered trademark of AbbVie Biotechnology Ltd.
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For more information, call 1-800 2-RINVOQ (1-800-274-6867) or go to www.RINVOQ.com.
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