

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

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

RINVOQ can cause serious side effects, including:

1. Serious Infections.

RINVOQ is a medicine that affects your immune system. RINVOQ 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.
- Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with RINVOQ.
- You should not start taking RINVOQ 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, 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. 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	• muscle aches	• cough
• shortness of breath	• feeling tired	• weight loss
• warm, red, or painful skin or sores on your body	• blood in your phlegm	• burning when you urinate or urinating more often than usual
	• diarrhea or stomach pain	

After starting RINVOQ, call your healthcare provider right away if you have any symptoms of an infection. RINVOQ 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 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 is a JAK inhibitor medicine.

3. Cancer and immune system problems.

RINVOQ 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. 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. 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, 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 (thrombosis).

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. 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, 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, stop taking RINVOQ 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 can get tears in their stomach or intestines. This happens most often in people who take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.
- Get medical help right away if you get stomach-area pain, fever, chills, nausea, or vomiting.

8. Changes in certain laboratory test results.

Your healthcare provider should do blood tests before you start taking RINVOQ and while you take RINVOQ 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, 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 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 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?**” for more information about side effects.

What is RINVOQ?

RINVOQ 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.
- 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.
- 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 safe and effective in children 12 years of age and older weighing at least 88 pounds (40 kg) with atopic dermatitis.

It is not known if RINVOQ is safe and effective in children under 18 years of age with juvenile idiopathic arthritis or with psoriatic arthritis.

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

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

Before taking RINVOQ, 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?”**
- 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 low red or white blood cell counts.
- have recently received or are scheduled to receive an immunization (vaccine). People who take RINVOQ should not receive live vaccines.
- are pregnant or plan to become pregnant. Based on animal studies, RINVOQ 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.
 - You should use effective birth control (contraception) to avoid becoming pregnant during treatment with RINVOQ and for 4 weeks after your last dose of RINVOQ.
 - Tell your healthcare provider if you think you are pregnant or become pregnant during treatment with RINVOQ.
 - If you take RINVOQ during pregnancy, contact AbbVie Inc. at 1-800-633-9110, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch to provide information about the health of you and your baby.
- are breastfeeding or plan to breastfeed. RINVOQ may pass into your breast milk. You and your healthcare provider should decide if you will take RINVOQ or breastfeed. **Do not** breastfeed during treatment with RINVOQ and for 6 days after your last dose of RINVOQ.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RINVOQ 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 in your blood.
- rifampicin (for bacterial infections) or phenytoin (for neurological disorders) as these medicines may decrease the effect of RINVOQ.
- 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?

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

What are the possible side effects of RINVOQ?

RINVOQ may cause serious side effects, including:

- See **“What is the most important information I should know about RINVOQ?”**

The most common side effects of RINVOQ in people treated for rheumatoid arthritis and psoriatic 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

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
- increased blood levels of creatine phosphokinase
- cough
- allergic reactions
- inflammation of hair follicles
- nausea
- stomach-area (abdominal) pain
- fever
- increased weight
- shingles (herpes zoster)
- flu
- tiredness
- low white blood cell count (neutropenia)
- muscle pain
- flu-like illness

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.

These are not all the possible side effects of RINVOQ.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store RINVOQ?

- Store RINVOQ at 36°F to 77°F (2°C to 25°C).
- Store RINVOQ in the original bottle to protect it from moisture.
- **Keep RINVOQ and all medicines out of the reach of children.**

General information about the safe and effective use of RINVOQ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RINVOQ for a condition for which it was not prescribed.

Do not give RINVOQ 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 that is written for health professionals.

What are the ingredients in RINVOQ 15 mg tablets?

Active ingredient: upadacitinib

Inactive ingredients: colloidal silicon dioxide, ferrousferic 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.

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For more information, call 1-800 2-RINVOQ (1-800-274-6867) or go to www.RINVOQ.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration
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