Getting started

Use this checklist to start and stay on track with your prescribed treatment plan.

1 Identify your specialty pharmacy

A specialty pharmacy will fill your RINVOQ prescription and arrange delivery.

- [ ] Ask your healthcare professional for the name and phone number of your specialty pharmacy.
- [ ] Write down the information so you can find it easily when you need it.
- [ ] Talk to your healthcare professional about getting RINVOQ approved by your health insurance company.

Specialty Pharmacy Name:

_____

Specialty Pharmacy Phone:

_____

2 Meet your Ambassador

Expect a call from your Ambassador to help navigate your health insurance coverage and find ways you may be able to save.

1-to-1 support from someone who has your back.

- [ ] Talk to your RINVOQ Complete Ambassador.* They will call you within one business day after enrollment, but if you need help sooner, reach out at **1.800.2RINVOQ** (1.800.274.6867).†
- [ ] Write down your Ambassador's name and phone number, or save it in your contacts/address book so you can find it easily.
- [ ] Talk to your Ambassador about how to take and store RINVOQ as prescribed by your doctor, or finding ways to fit RINVOQ into your everyday routine.

Ambassador Name:

_____

Ambassador Phone:

_____

3 Get prepared with additional resources

Explore all the ways RINVOQ Complete can give you support on your terms.

- [ ] Download the RINVOQ Complete App to help you stay on track with your prescribed treatment plan, set medication reminders, and log your progress to share with your doctor.
- [ ] Visit ExploreRINVOQComplete.com for more resources.

Download the Complete App

Use your phone's camera to scan the QR code to download the App.

Or, search for "Complete App" at the App Store® or Google Play™.

Download on the App Store

GET IT ON Google Play

Not enrolled? Sign up today at EnrollRINVOQComplete.com.

*Nurse Ambassadors are provided by AbbVie and do not work under the direction of your health care professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

†Help is available Monday through Friday from 8 am to 8 pm ET, except for holidays.

Please see Use and Important Safety Information, including BOXED WARNING, on page 2.

Please see full Prescribing Information, including Medication Guide, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf, and talk to your doctor.

RINVOQ® upadacitinib

USE AND IMPORTANT SAFETY INFORMATION[1]

USE[1]

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

IMPORTANT SAFETY INFORMATION[1]

What is the most important information I should know about RINVOQ? RINVOQ may cause serious side effects, including:

- **Serious infections.** RINVOQ can lower your ability to fight infections. Serious infections have happened 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 (HCP) should test you for TB before starting RINVOQ and check 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 HCP tells you it is okay. If you get a serious infection, your HCP may stop your treatment until your infection is controlled. You may be at higher risk of developing shingles (herpes zoster).
- **Increased risk of death in people 50 years and older who have at least 1 heart disease (cardiovascular) risk factor.**
- **Cancer and immune system problems.** RINVOQ may increase your risk of certain cancers. Lymphoma and other cancers, including skin cancers, can happen. Current or past smokers are at higher risk of certain cancers, including lymphoma and lung cancer. Follow your HCP's advice about having your skin checked for skin cancer during treatment with RINVOQ. Limit the amount of time you spend in sunlight. Wear protective clothing when you are in the sun and use sunscreen.
- **Increased risk of major cardiovascular (CV) events, such as heart attack, stroke, or death, in people 50 years and older who have at least 1 heart disease (CV) risk factor, especially if you are a current or past smoker.**
- **Blood clots.** Blood clots in the veins of the legs or lungs and arteries can happen with RINVOQ. This may be life-threatening and cause death. Blood clots in the veins of the legs and lungs have happened more often in people who are 50 years and older and with at least 1 heart disease (CV) risk factor.
- **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.
- **Tears in the 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.
- **Changes in certain laboratory tests.** Your HCP should do blood tests before you start taking RINVOQ and while you take it. Your HCP may stop your RINVOQ treatment for a period of time if needed because of changes in these blood test results.

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

What should I tell my HCP BEFORE starting RINVOQ?

Tell your HCP if you:

- Are being treated for an infection, have an infection that won't go away or keeps coming back, 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 phlegm
  - Diarrhea or stomach pain
  - Cough
  - Weight loss
  - Burning when urinating or urinating more often than normal
- Have TB or have been in close contact with someone with TB.
- Are a current or past smoker.
- Have had a heart attack, other heart problems, or stroke.
- Have or have had any type of cancer, hepatitis B or C, shingles (herpes zoster), blood clots in the veins of your legs or lungs, diverticulitis (inflammation in parts of the large intestine), or ulcers in your stomach or intestines.
- Have other medical conditions, including liver problems, low blood cell counts, diabetes, chronic lung disease, HIV, or a weak immune system.
- Live, have lived, or have traveled to parts of the country, such as the Ohio and Mississippi River valleys and the Southwest, that increase your risk of getting certain kinds of fungal infections. If you are unsure if you've been to these types of areas, ask your HCP.
- Have recently received or are scheduled to receive a 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. Your HCP will check whether or not you are pregnant before you start RINVOQ. You should use effective birth control (contraception) to avoid becoming pregnant during treatment with RINVOQ and for 4 weeks after your last dose.
- There is a pregnancy surveillance program for RINVOQ. The purpose of the program is to collect information about the health of you and your baby. If you become pregnant while taking RINVOQ, you are encouraged to report the pregnancy by calling 1-800-633-9110.
- Are breastfeeding or plan to breastfeed. RINVOQ may pass into your breast milk. Do not breastfeed during treatment with RINVOQ and for 6 days after your last dose.

Tell your HCP 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 HCP if you take:

- Medicines for fungal or bacterial infections
- Rifampicin or phenytoin
- Medicines that affect your immune system

If you are not sure if you are taking any of these medicines, ask your HCP or pharmacist.

What should I avoid while taking RINVOQ?

Avoid food or drink containing grapefruit during treatment with RINVOQ as it may increase the risk of side effects.

What should I do or tell my HCP AFTER starting RINVOQ?

- Tell your HCP right away if you have any symptoms of an infection. RINVOQ can make you more likely to get infections or make any infections you have worse.
- 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
- Tell your HCP right away if you have any signs or 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
- Tell your HCP right away if you have a fever or stomach-area pain that does not go away, and a change in your bowel habits.

What are other possible side effects of RINVOQ?

Common side effects 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, swelling of the feet and hands (peripheral edema), increased blood levels of creatine phosphokinase, allergic reactions, inflammation of hair follicles, stomach-area (abdominal) pain, increased weight, flu, tiredness, lower number of certain types of white blood cells (neutropenia, lymphopenia, leukopenia), muscle pain, flu-like illness, rash, increased blood cholesterol levels, increased liver enzyme levels, pneumonia, low number of red blood cells (anemia), and infection of the stomach and intestine (gastroenteritis). A 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 HCP right away if you have any sudden changes in your vision during treatment with RINVOQ. 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.

How should I take RINVOQ?

RINVOQ is taken once a day with or without food. Do not split, crush, or chew the tablet. Take RINVOQ exactly as your HCP tells you to use it. RINVOQ is available in 15 mg, 30 mg, and 45 mg extended-release tablets.

This is the most important information to know about RINVOQ. For more information, talk to your HCP.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/PatientAccessSupport to learn more.

Reference: 1. RINVOQ [package insert]. North Chicago, IL: AbbVie Inc.

Please see full Prescribing Information, including Medication Guide, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf, and discuss with your doctor.

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US-RNQD-250348

RINVOQ® upadacitinib

RINVOQ® COMPLETE

Faxing Instructions:
Fax to RINVOQ Complete **(1.678.727.0690)**

Enrollment and Prescription Form

RD-022326-AP01

The healthcare professional (HCP) and the patient or legal guardian should fill out this form completely before leaving the office.
Sections in **GOLD** (1,2,3,4) are necessary for enrollment into RINVOQ Complete. Required fields are marked with an asterisk (*).

1 PATIENT'S INFORMATION Please print clearly.

First Name*: _____ Last Name*: _____ Date of Birth (MM/DD/YYYY)*: ___/___/_____ Gender*: (check one) ☐M ☐F

Name of Patient's Legal Guardian*: _____ Relationship to Patient: _____ ☐Spanish interpreter needed

Patient or Legal Guardian's Address*: _____ City*: _____ State*: _____ ZIP*: _____

Patient or Guardian's Mobile Phone*: _____ Patient or Legal Guardian's Email Address*: _____

When did the patient start on treatment?* ☐Not Yet Started ☐0–3 Months Ago ☐4–6 Months Ago ☐7–12 Months Ago ☐Over 12 Months Ago

Privacy Notice: For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit **https://abbv.ie/PrivacyPatient**.

Consent to process my sensitive personal information: Through my submission of the RINVOQ Complete Enrollment and Prescription form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the **"How We May Disclose Personal Data"** section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **"Your Privacy Choices"** on AbbVie's website.

▶ ☐ **Marketing consent:** I consent to the collection, use, and disclosure of my health-related personal data to receive communications from AbbVie regarding its products, programs, services, clinical trials, research opportunities and for online targeted advertising, as further described in the **"How we may use Personal Data," "How we disclose Personal Data,"** and **"Cookies and similar tracking and data collection technologies"** sections of our **Privacy Notice**. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting **"Your Privacy Choices"** on AbbVie's website.

▶ ☐ **Texting consent:** I consent to receive Complete Treatment Support automated and recurring text messages from AbbVie, including services updates and marketing messages, refill reminders and prescription notifications to the above mobile number. Message and data rates may apply. I am not required to consent as a condition of receiving goods or services. I can reply HELP for help. I can reply STOP to opt out at any time. View **Privacy Notice** and mobile T&C at **https://abbv.ie/USMobileTerms**

By enrolling, you may receive your own Nurse Ambassador provided by AbbVie. Ambassadors do not work under the direction of your health care professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

2 INSURANCE INFORMATION Please attach insurance and prescription insurance cards if available.

▼ FOR HEALTHCARE PROVIDER USE ONLY ▼

3 DIAGNOSIS* ☐Moderate to Severe Atopic Dermatitis (AD) Date of Diagnosis: ___/___/_____

4 PRESCRIBER INFORMATION

Prescriber's Name (First, Last)*: _____ Office Phone*: _____ Address*: _____

Office Contact Name*: _____ City*: _____

NPI #*: _____ Office Fax*: _____ State*: _____ ZIP*: _____

Privacy Notice: For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit **https://abbv.ie/PrivacyHCP**

5 CLINICAL INFORMATION Fax any necessary clinical/office notes to the preferred Specialty Pharmacy only.

Prior Therapies (select all that apply): ☐Topical Corticosteroid ☐Topical Calcineurin Inhibitor
☐Immunosuppressant (e.g., methotrexate, cyclosporine, etc.) ☐Oral Corticosteroid (e.g., prednisone, etc.)
☐Biologics (e.g., Dupixent, Adbry, etc.) ☐Oral JAK Inhibitors (e.g., Cibinqo, etc.)

Weight: _____

TB Test Date: ___/___/_____ ☐Pos ☐Neg

6 PHARMACY PRESCRIPTION - (Optional) Fill out and sign corresponding prescription below.

Patient's preferred Specialty Pharmacy: _____ ☐Check if faxed to Specialty Pharmacy

☐RINVOQ 15 mg extended-release tablets
1 tablet (15 mg) p.o. once daily

☐RINVOQ 30 mg† extended-release tablets
1 tablet (30 mg) p.o. once daily

†Only for AD patients 12 to <65 years weighing at least 40 kgs, who had an inadequate response to 15 mg once daily and who are not taking strong CYP3A4 inhibitors and do not have severe renal impairment. Discontinue RINVOQ if an adequate response is not achieved with the 30 mg dose. Use the lowest effective dose needed to maintain response.

Quantity: ☐30 ☐90

Refills: _____

PRESCRIBER CERTIFICATION: I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed RINVOQ to the previously identified patient and that I provided the patient with a description of the RINVOQ Complete patient support program. I authorize RINVOQ Complete to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan (if applicable).

Prescriber's Signature: (REQUIRED)* X _____ **Date*:** ___/___/_____

7 RINVOQ COMPLETE PRESCRIPTION - Required in the event a patient experiences an insurance delay or denial

Eligible patients must have (1) commercial insurance, (2) a valid Rx for RINVOQ, and (3) experienced a delay or denial in insurance determination.
See program Terms and Conditions on the following page. Please complete the full form as well as this section and sign below.
Prescription to be filled through an AbbVie-authorized pharmacy. I understand that faxing this form to RINVOQ Complete will result in an original copy being simultaneously transmitted to the AbbVie-authorized pharmacy under this section.

☐RINVOQ 15 mg extended-release tablets
1 tablet (15 mg) p.o. once daily

☐RINVOQ 30 mg† extended-release tablets
1 tablet (30 mg) p.o. once daily

†Only for AD patients 12 to <65 years weighing at least 40 kgs, who had an inadequate response to 15 mg once daily and who are not taking strong CYP3A4 inhibitors and do not have severe renal impairment. Discontinue RINVOQ if an adequate response is not achieved with the 30 mg dose. Use the lowest effective dose needed to maintain response.

Quantity: 30

Refills: _____

PRESCRIBER CERTIFICATION: I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed RINVOQ to the previously identified patient and that I provided the patient with a description of the RINVOQ Complete patient support program. I authorize RINVOQ Complete to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy. I understand that the no charge resource through RINVOQ Complete may support patients who are experiencing a delay in insurance coverage for RINVOQ until coverage is obtained, and I confirm that I will support the above-identified patient in seeking to secure such coverage as I deem appropriate. I certify that I will not seek reimbursement from any third party payor for any no charge product dispensed by an AbbVie authorized pharmacy.

Prescriber's Signature: (REQUIRED)* X _____ **Date*:** ___/___/_____

Please see Indication and Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on page 4.
Please see full Prescribing Information, including BOXED WARNING, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

US-RNQD-250348

RINVOQ® upadacitinib

RINVOQ® COMPLETE

INDICATION AND IMPORTANT SAFETY INFORMATION FOR HEALTHCARE PROVIDERS[1]

INDICATION[1]

RINVOQ is indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

IMPORTANT SAFETY INFORMATION[1]

SERIOUS INFECTIONS

Patients treated with RINVOQ are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids. If a serious infection develops, interrupt RINVOQ until the infection is controlled.

Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Test patients for latent TB before RINVOQ use and during therapy. Consider treatment for latent TB infection prior to RINVOQ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of treatment with RINVOQ prior to initiating therapy in patients with chronic or recurrent infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with RINVOQ, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

MORTALITY

In a large, randomized, postmarketing safety study comparing another Janus kinase (JAK) inhibitor with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years old with at least one cardiovascular (CV) risk factor, a higher rate of all-cause mortality, including sudden CV death, was observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with RINVOQ.

In a large, randomized, postmarketing safety study comparing another JAK inhibitor with TNF blockers in RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]), lymphomas, and lung cancer (in current or past smokers) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk.

With RINVOQ, consider the benefits and risks for the individual patient prior to initiating or continuing therapy, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers. NMSCs have been reported in patients treated with RINVOQ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer. Advise patients to limit sunlight exposure by wearing protective clothing and using sunscreen.

MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE)

In a large, randomized, postmarketing study comparing another JAK inhibitor with TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) was observed with the JAK inhibitor. Patients who are current or past smokers are at additional increased risk. Discontinue RINVOQ in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with RINVOQ, particularly in patients who are current or past smokers and patients with other CV risk factors. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

THROMBOSIS

Thromboses, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated for inflammatory conditions with JAK inhibitors, including RINVOQ. Many of these adverse events were serious and some resulted in death.

In a large, randomized, postmarketing study comparing another JAK inhibitor to TNF blockers in RA patients ≥50 years old with at least one CV risk factor, a higher rate of thrombosis was observed with the JAK inhibitor. Avoid RINVOQ in patients at risk. Patients with symptoms of thrombosis should discontinue RINVOQ and be promptly evaluated.

HYPERSENSITIVITY

RINVOQ is **contraindicated** in patients with known hypersensitivity to upadacitinib or any of its excipients. Serious hypersensitivity reactions, such as anaphylaxis and angioedema, were reported in patients receiving RINVOQ in clinical trials. If a clinically significant hypersensitivity reaction occurs, discontinue RINVOQ and institute appropriate therapy.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal (GI) perforations have been reported in clinical trials with RINVOQ. Monitor RINVOQ-treated patients who may be at risk for GI perforation (e.g., patients with a history of diverticulitis and patients taking NSAIDs or corticosteroids). Promptly evaluate patients presenting with new onset abdominal pain for early identification of GI perforation.

LABORATORY ABNORMALITIES

Neutropenia

Treatment with RINVOQ was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3). Treatment with RINVOQ is not recommended in patients with an ANC <1000 cells/mm^3. Evaluate neutrophil counts at baseline and thereafter according to routine patient management.

Lymphopenia

Absolute lymphocyte counts (ALC) <500 cells/mm^3 were reported in RINVOQ-treated patients. Treatment with RINVOQ is not recommended in patients with an ALC <500 cells/mm^3. Evaluate at baseline and thereafter according to routine patient management.

Anemia

Decreases in hemoglobin levels to <8 g/dL were reported in RINVOQ-treated patients. Treatment should not be initiated or should be interrupted in patients with hemoglobin levels <8 g/dL. Evaluate at baseline and thereafter according to routine patient management.

Lipids

Treatment with RINVOQ was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Manage patients according to clinical guidelines for the management of hyperlipidemia. Evaluate patients 12 weeks after initiation of treatment and thereafter according to the clinical guidelines for hyperlipidemia.

Liver enzyme elevations

Treatment with RINVOQ was associated with increased incidence of liver enzyme elevation compared to placebo. Evaluate at baseline and thereafter according to routine patient management. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases in aspartate aminotransferase (AST) or alanine aminotransferase (ALT) are observed during routine patient management and drug-induced liver injury is suspected, RINVOQ should be interrupted until this diagnosis is excluded.

EMBRYO-FETAL TOXICITY

Based on findings in animal studies, RINVOQ may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RINVOQ and for 4 weeks after the final dose. Verify pregnancy status of females of reproductive potential prior to starting treatment with RINVOQ.

VACCINATION

Avoid use of live vaccines during, or immediately prior to, RINVOQ therapy. Prior to initiating RINVOQ, patients should be brought up to date on all immunizations, including prophylactic varicella zoster or herpes zoster vaccinations, in agreement with current immunization guidelines.

MEDICATION RESIDUE IN STOOL

Reports of medication residue in stool or ostomy output have occurred in patients taking RINVOQ. Most reports described anatomic or functional GI conditions with shortened GI transit times. Instruct patients to contact their healthcare provider if medication residue is observed repeatedly. Monitor patients clinically and consider alternative treatment if there is an inadequate therapeutic response.

LACTATION

There are no data on the presence of RINVOQ in human milk, the effects on the breastfed infant, or the effects on milk production. Available data in animals have shown the excretion of RINVOQ in milk. Advise patients that breastfeeding is not recommended during treatment with RINVOQ and for 6 days after the last dose.

HEPATIC IMPAIRMENT

RINVOQ is not recommended for use in patients with severe hepatic impairment.

ADVERSE REACTIONS

The most common adverse reactions in RINVOQ clinical trials were upper respiratory tract infections, herpes zoster, herpes simplex, bronchitis, nausea, cough, pyrexia, acne, headache, peripheral edema, increased blood creatine phosphokinase, hypersensitivity, folliculitis, abdominal pain, increased weight, influenza, fatigue, neutropenia, myalgia, influenza-like illness, elevated liver enzymes, rash, and anemia.

Inform patients that retinal detachment has been reported in clinical trials with RINVOQ. Advise patients to immediately inform their healthcare provider if they develop any sudden changes in vision while receiving RINVOQ.

Dosage Forms and Strengths: RINVOQ is available in 15 mg, 30 mg, and 45 mg extended-release tablets.

TERMS AND CONDITIONS

Eligibility criteria: Available to patients aged 63 or younger with commercial insurance coverage. Patients must have a valid prescription for RINVOQ® (upadacitinib) for an FDA approved indication and a denial of insurance coverage based on a prior authorization request on file along with a confirmation of appeal. Continued eligibility for the program requires the submission of an appeal of the coverage denial every 180 days. Program provides for RINVOQ® (upadacitinib) at no charge to patients for up to two years or until they receive insurance coverage approval, whichever occurs earlier, and is not contingent on purchase requirements of any kind. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Offer subject to change or discontinuance without notice. This is not health insurance and program does not guarantee insurance coverage. No claims for payment may be submitted to any third party for product dispensed by program. Limitations may apply.

Reference: 1. RINVOQ [package insert]. North Chicago, IL: AbbVie Inc.

Please see full Prescribing Information, including BOXED WARNING, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

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US-RNQD-250348

RINVOQ® upadacitinib