



# You may have questions about RINVOQ. That's why RINVOQ Complete is here to help you:

- Make sense of your insurance coverage
- Identify ways you may save on RINVOQ
- Find ways to incorporate RINVOQ into your routine
- Get resources to track your progress

Your RINVOQ Complete Ambassador\* is committed to helping you understand your treatment, answering your questions, and supporting you in achieving your personal goals. Your Ambassador will be there every step of the way, for as long as you need while on RINVOQ.

# You've signed up for RINVOQ Complete. Here's what to do next:



**Before you leave the office, ask your health care professional** which Specialty Pharmacy your prescription is being sent to and write down the number below. This pharmacy will help fill your RINVOQ prescription and arrange delivery.

SPECIALTY PHARMACY:	PHONE:



**Expect a call from your Ambassador within 1 business day** (call may come from AbbVie). They'll help you navigate the prescription process and help you start and stay on track with your prescribed treatment plan.



**FOR QUESTIONS**, or if you have not yet connected with your Ambassador, please call **1.800.2RINVOQ** (1.800.274.6867).

\*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.

The categories of personal information collected on this Enrollment and Prescription Form include name, date of birth, address, Rx, and insurance information. The personal information collected will be used for program enrollment and to conduct research and analytics on a de-identified basis. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit https://privacy.abbvie.

Please see <u>Use and Important Safety Information</u> on page 2.

Please see full <u>Prescribing Information</u>, including <u>Medication Guide</u>, or visit <u>https://www.rxabbvie.com/pdf/rinvoq\_pi.pdf</u>, and discuss with your doctor.



# USE AND IMPORTANT SAFETY INFORMATION<sup>1</sup>

## **USE**<sup>1</sup>

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. 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 12 years of age with atopic dermatitis.

#### IMPORTANT SAFETY INFORMATION

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
- -Muscle aches -Feeling tired -Blood in phlegm -Diarrhea or
- -Cough -Weight loss -Burning when urinating or
- -Warm, red, or painful skin or sores stomach pain on your body
- 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 iaw
- Pain or discomfort in your arms, back, neck, jaw, or stomach
- 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

-Shortness of breath with or

without chest discomfort

- Nausea or vomiting

-Feeling lightheaded

-Slurred speech

-Weakness in one part or

on one side of your body

-Breaking out in a cold sweat

- 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, 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/myAbbVieAssist 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.







# **Enrollment and Prescription Form**

RD-060923-AP06

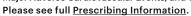
Sections in GOLD (1,2,3,4) are necessary for enrollment into RINVOQ Complete. Required fields are marked with an asterisk (\*).

The health care professional (HCP) and the patient or legal guardian should fill out this form completely before leaving the office.

PATIENT'S INFORMATION Please print clea	rly.						
First Name*: Last	t Name*:	Date of Birth*: /	/	Gend	ler: (check on	e) 🗆 N	M □F
Name of Patient's Parent or Guardian*:		Relationship to Patient:					
Address*:		City*:		State*	·: Z	ZIP*:	
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☐ I consent to receive automated and recurring text and data rates may apply. My consent is not a con							
When did the patient start on treatment?*	Not Yet Started □ 0-3 Month	s Ago 4-6 Months Ago	□ 7-1:	2 Months Ago 🗆 Over	12 Months Ag	0	
By enrolling, you may receive your own Nurse Am medical advice. They are trained to direct patients this form include name, date of birth, address, I research and analytics on a de-identified basis AbbVie uses personal information, visit <a href="https://www.https://www&lt;/th&gt;&lt;th&gt;to their HCP for treatment-related a Rx, and insurance information. The For more information about the&lt;/th&gt;&lt;th&gt;advice, including further referra&lt;br&gt;ne personal information colle&lt;/th&gt;&lt;th&gt;als. 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I certi I provided the patient with a descrip behalf for the purposes of transmitt RINVOQ Complete may support pat I confirm that I will support the above seek reimbursement from any third&lt;/td&gt;&lt;td&gt;fy that I am the prescriber who ha&lt;br&gt;tion of the RINVOQ Complete pa&lt;br&gt;ing this prescription to the appro&lt;br&gt;ients who are experiencing a del:&lt;br&gt;re-identified patient in seeking to&lt;/td&gt;&lt;td&gt;as presc&lt;br&gt;atient su&lt;br&gt;opriate p&lt;br&gt;lay in ins&lt;br&gt;o secure&lt;/td&gt;&lt;td&gt;ribed RINVOQ to the previou&lt;br&gt;pport program. I authorize R&lt;br&gt;harmacy. I understand that t&lt;br&gt;urance coverage for RINVOC&lt;br&gt;such coverage as I deem ap&lt;/td&gt;&lt;td&gt;isly identified p&lt;br&gt;INVOQ Comple&lt;br&gt;he no charge re&lt;br&gt;Q until coverage&lt;br&gt;propriate. 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IMPORTANT INFORMATION: The categories of personal information collected on this form include prescriber name, address, NPI, etc. The personal information collected will be used for program management and to perform research and analytics. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit <a href="https://privacy.abbvie.">https://privacy.abbvie.</a> Please share this information with your patient.

Please see Indication and Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on page 4.





# INDICATION AND IMPORTANT SAFETY INFORMATION

## INDICATION<sup>1</sup>

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<sup>1</sup>

#### **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

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 major adverse cardiovascular events (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**

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. 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 gastrointestinal 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/mm³). Treatment with RINVOQ is not recommended in patients with an ANC <1000 cells/mm³. Evaluate neutrophil counts at baseline and thereafter according to routine patient management.

#### Lymphopenia

Absolute lymphocyte counts (ALC) <500 cells/mm³ were reported in RINVOQ-treated patients. Treatment with RINVOQ is not recommended in patients with an ALC <500 cells/mm³. 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 varicella zoster or prophylactic 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, 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.

## RINVOQ Complete Prescription Terms and Conditions

Eligibility criteria: Available to patients aged 63 or younger with commercial insurance coverage. Patients must have a valid prescription for RINVOQ® (upadactinib) 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.





