

You or your child 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 child's routine
- Get resources to track your child's progress

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

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



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

SPECIALTY PHARMACY:	PHONE:



Expect a call from your child's Nurse Ambassador within 1 business day (the call may come from any area code). They'll help navigate the prescription process and help your child start and stay on track with their prescribed treatment plan.



FOR QUESTIONS, or if you have not yet connected with your child's Nurse 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 in this Enrollment and Prescription Form include contact, insurance, prescription, and medical history information. The personal information collected will be used to provide and manage the RINVOQ Complete program and to perform 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 www.abbvie.com/privacy.html.

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 child's doctor.





USE AND IMPORTANT SAFETY INFORMATION about RINVOQ® (upadacitinib)¹

USE1

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 about RINVOQ® (upadacitinib)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 and 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.

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.
- 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 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 the common side effects of RINVOQ?

These 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, low white blood cell count (neutropenia), muscle pain, and flu-like illness.

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.

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, break, crush, or chew the tablet. Take RINVOQ exactly as your HCP tells you to use it. RINVOQ is available in 15 mg and 30 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 <u>AbbVie.com/myAbbVieAssist</u> to learn more.

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

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 child's doctor.







Enrollment and Prescription Form

RAD-EMA2722-P02

Faxing Instructions:

1. Fax to RINVOQ Complete (1.678.727.0690)
2. Fax to the patient's preferred Specialty Pharmacy Questions? Call 1.800.274.6867

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 - To be completed	d by the child's parent or	legal guardian. Please print clearly.	
First Name*: Last	: Name*:	Date of Birth: / /	Gender: (check one) ☐ M ☐ F
Name of Patient's Parent or Guardian*:		Relationship to Patient:	
Address*:		City*:	State*: ZIP*:
Home Phone*: Parent/Guardian M	obile Phone:	Parent/Guardian Email Address*:	☐ Spanish interpreter needed
☐ I consent to receive recurring text messages from rates may apply. My consent is not a condition of	m AbbVie, including service f receiving goods or service	e updates, medication reminders and marketi es. I can reply HELP for help. I can text STOP t	ing messages, to the above mobile number. Message and data o unsubscribe any time. View full Terms and Conditions .
Best Time to Call (Monday-Friday): ☐ Anyti	me ☐ Morning ☐ Aft	ernoon 🗆 Evening Evelia ipit volla vide	ebis doluptae modiscit omnis audi quam dit offictas asQu
When did the patient start on treatment?*	□ Not Yet Started □ C	0-3 Months Ago \Box 4-6 Months Ago \Box	7-12 Months Ago 🔲 Over 12 Months Ago
	atients to their HCP for tr		ne direction of your health care professional (HCP) or referrals. To learn about AbbVie's privacy practices and
☐ I would like to receive news and updates about	AbbVie's products, clinica	ll trials, research opportunities, programs, a	nd other information that may be of interest to me.
INSURANCE INFORMATION	f your doctor's office will	copy and attach insurance cards.	
Beneficiary/Cardholder Name:		Prescription Insurance:	
Medical Insurance:			
Medical Insurance ID #:		Rx ID #:	
Group #:		Rx Bin #:	Rx PCN #:
	▼ FOR HEAL	TH CARE PROVIDER USE ONLY ▼	
DIAGNOSIS* ☐ Moderate to Severe Atopic D	ermatitis (AD)	-10: Date of Diagno	osis:/
PRESCRIBER INFORMATION I would like to	receive a copy: Bei	nefits Verification Summary	horization Form
Prescriber's Name (First, Last)*:	Office Phone*:		Address*:
	Office Contact Na	me:	City*: State*: ZIP*:
NPI #*:	Office Fax*:		Email:
CLINICAL INFORMATION			
Prior Therapies:	_ Concomitant Med	ications:	TB Test (Date):/ Pos Neg
Weight:	Drug Allergies:		Fax any necessary clinical/office notes to the
Atopic Dermatitis: BSA ☐ under 10% ☐ 10% or more			preferred Specialty Pharmacy only.
			•
PHARMACY PRESCRIPTION - (Optional) Fill	out and sign correspon	iding prescription below.	
Patient's preferred Specialty Pharmacy:		CI	heck 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 12–65 years who had an inadequate response to 15 mg once daily and	(15 mg) p.o. once daily accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed RINVOQ to the previously identified patient (30 mg) p.o. once daily AD patients 12-65 years who had an te response to 15 mg once daily and		
who are not taking strong CYP3A4 inhibitors		Date*: / /	
Quantity: □30 □90			
Refills:			
PINIO COMPLETE PRECORIPTION P. :			
RINVOQ COMPLETE PRESCRIPTION - Requir	ed in the event a patient e	experiences an insurance delay or denial	
Eligible patients must have (1) commercial insur See program Terms and Conditions on the follor Prescription to be filled through an AbbVie-auth simultaneously transmitted to the AbbVie-authc	wing page. Please complete orized pharmacy. I unde	ete the full form as well as this section and rstand that faxing this form to RINVOQ Co	d sign below.
☐ RINVOQ 15 mg extended-release tablets 1 tablet (15 mg) p.o. once daily	PRESCRIBER CERTIFIC	CATION: I certify that the above therapy is med	dically necessary and that the information provided is accurate escribed RINVOQ to the previously identified patient and that
RINVOQ 30 mg ⁺ extended-release tablets 1 tablet (30 mg) p.o. once daily †Only for AD patients 12-65 years who had an inadequate response to 15 mg once daily and who are not taking strong CYP3A4 inhibitors	I provided the patient with behalf for the purposes of RINVOQ Complete may su I confirm that I will support	a description of the RINVOQ Complete patient transmitting this prescription to the appropriate pport patients who are experiencing a delay in i t the above-identified patient in seeking to secu	support program. I authorize RINVOQ Complete to act on my e pharmacy. I understand that the no charge resource through insurance coverage for RINVOQ until coverage is obtained, and are such coverage as I deem appropriate. I certify that I will not t dispensed by an AbbVie authorized pharmacy.
and do not have severe renal impairment. Quantity: 30	Prescriber's Signature	e: (REQUIRED)*X	Date*: / /
Refills:			

IMPORTANT INFORMATION: By submitting this form you are referring the above patient to AbbVie's patient support program to determine eligibility and receive support related to an AbbVie product. AbbVie, its affiliates, collaborators and agents will use the information collected about you and your patient to provide the patient support and perform research and analytics, on a de-identified basis, for management of the program. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit www.abbvie.com/privacy.html. Please share this information with your patient.



INDICATION AND IMPORTANT SAFETY INFORMATION about RINVOQ® (upadacitinib)¹

INDICATION

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 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. In these trials, many patients with RA were receiving background therapy with

Please see full Prescribing Information.



nonsteroidal anti-inflammatory drugs (NSAIDs). Monitor RINVOQ-treated patients who may be at risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis or taking NSAIDs). 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 clinical studies. 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 clinical studies. 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.

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.

ADVERSEREACTIONS

The most common adverse reactions in RINVOQ clinical trials (≥1%) were upper respiratory tract infections, herpes zoster, herpes simplex, bronchitis, nausea, cough, pyrexia, acne, headache, blood creatine phosphokinase increased, hypersensitivity, folliculitis, abdominal pain, increased weight, influenza, fatigue, neutropenia, myalgia, and influenza-like illness.

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 and 30 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® (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 Medicaire, 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.

