

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
- Fit RINVOQ into your life
- Get resources to track your progress

Your RINVOQ Complete Nurse Ambassador* is committed to helping you understand your treatment, answering your questions, and supporting you to achieve your personal goals while on RINVOQ. Your Nurse Ambassador will be there every step of the way, starting with finding ways to save on the cost of your prescription.

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 its number below. This pharmacy will help fill your RINVOQ prescription and arrange delivery. SPECIALTY PHARMACY: PHONE:			
2	Expect a call from your Nurse Ambassador within one business day (call may come from any area code). They'll help you navigate the prescription process, understand your insurance coverage, and help you identify ways you may be able to save on RINVOQ.			
F	or questions, or if you have not yet connected with your Nurse Ambassador, please call 1.800.2RINVOQ (1.800.274.6867).			

*Ambassadors do not give medical advice and will direct you to your health care professional for any treatment-related questions, 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 Use and Important Safety Information on page 2.

Please see full <u>Prescribing Information</u>, including Medication Guide, and discuss with your doctor.





Use and Important Safety Information About RINVOQ™ (upadacitinib)¹

RINVOQ Use¹

RINVOQ is a prescription medicine used to treat adults with moderate to severe rheumatoid arthritis in whom methotrexate did not work well or could not be tolerated. It is not known if RINVOQ is safe and effective in children under 18 years of age.

Important Safety Information about RINVOQ¹

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

RINVOQ is a medicine that can lower the ability of your immune system to fight infections. You should not start taking RINVOQ if you have any kind of infection unless your healthcare provider (HCP) tells you it is okay.

- Serious infections have happened in some people 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 HCP should test you for TB before starting RINVOQ and check you closely for signs and symptoms of TB during treatment with RINVOQ. You may be at higher risk of developing shingles (herpes zoster).
- Lymphoma and other cancers, including skin cancers, can happen in people taking RINVOQ.
- Blood clots in the veins of the legs or lungs and arteries are possible in some people taking RINVOQ. This may be life-threatening and cause death.
- Tears in the stomach or intestines and changes in certain laboratory tests can happen. 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.

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.
- Have had any type of cancer, hepatitis B or C, shingles (herpes zoster), or 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 that increase your risk of getting certain kinds of fungal infections, such as the Ohio and Mississippi River valleys and the Southwest. If you are unsure if you've been to these 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 while taking RINVOQ and for at least 4 weeks after your last dose.
- Are breastfeeding or plan to breastfeed. RINVOQ may pass into your breast milk. You should not breastfeed while taking RINVOQ and for at least 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

Ask your HCP or pharmacist if you are not sure if you are taking any of these medicines.

What should I 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.
- Have any signs or symptoms of blood clots during treatment with RINVOQ, including:
- Swelling
- Pain or tenderness in the leg
- Sudden unexplained chest pain
- Shortness of breath
- 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), nausea, cough, and fever. These are not all the possible side effects of 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.

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 <u>Prescribing Information</u>, including Medication Guide, and discuss with your doctor.







Enrollment and Prescription Form

Sections in GOLD (1, 2, 3, 4) denote fields required for enrollment in RINVOQ Complete. The HCP and the patient or legally authorized person should fill out this form completely before leaving the office.

1. Fax to RINVOQ Complete (1.678.727.0690)

Faxing Instructions:

2. Fax to the patient's preferred Specialty Pharmacy Questions? Call 1.800.274.6867

	completed by patient or legally authorized	person. Please print clearly.			
First Name:	Last Name:	Date of Birth: / /	Gender: (check one) ☐ M ☐ F		
Address:		City:	State: ZIP:		
Phone:		Email Address:			
Best Time to Call: Monday-Friday	☐ Anytime ☐ Morning ☐ Afternoo	n □ Evening □ Check here	only if it is <u>not</u> okay to leave a message		
When did you start on treatment?	□ Not Yet Started □ 0-3 Months Ago	□ 4-6 Months Ago □ 7-12 I	Months Ago □ Over 12 Months Ago		
By enrolling, you may receive your or	wn Nurse Ambassador Ambassadors do not	give medical advice and are tra	lined to direct patients to their health care professionals		
		_	y choices, visit <u>www.abbvie.com/privacy.html</u>		
☐ I would like to receive news and up	odates about AbbVie's products, clinical trial	s, research opportunities, prograr	ms, and other information that may be of interest to me.		
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DIAGNOSIS ☐ Moderate to Severe	e Rheumatoid Arthritis (RA) (M05) Date	of Diagnosis:/			
PRESCRIBER INFORMATION WOL	uld like to receive a copy: Benefits Veri	ification summary □ Prior Auth	norization form		
Prescriber's Name* (First, Last):	' '				
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CLINICAL INFORMATION					
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			gn below. Complete will result in an original copy being		
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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 $for which AbbVie \ uses \ personal \ information, \ visit \ \underline{www.abbvie.com/privacy.html}. \ Please \ share \ this \ information \ with \ your \ patient.$



Indication and Important Safety Information¹

INDICATION1

RINVOQ is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

Limitation of Use: Use of RINVOQ in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

IMPORTANT SAFETY INFORMATION¹

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 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.

MALIGNANCY

Lymphoma and other malignancies have been observed in patients treated with RINVOQ. Consider the risks and benefits of treatment with RINVOQ prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or in patients who develop a malignancy. NMSCs have been reported in patients treated with RINVOQ. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death. Consider the risks and benefits prior to treating patients who may be at increased risk. Patients with symptoms of thrombosis should be promptly evaluated.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal perforations have been reported in clinical studies with RINVOQ, although the role of JAK inhibition in these events is not known. In these studies, many patients with rheumatoid arthritis were receiving background therapy with nonsteroidal anti-inflammatory drugs (NSAIDs). RINVOQ should be used with caution in patients who may be at increased risk for gastrointestinal perforation. Promptly evaluate patients presenting with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES

Neutropenio

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 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 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

Use of live, attenuated vaccines during, or immediately prior to, RINVOQ therapy is not recommended. Prior to initiating RINVOQ, patients should be brought up to date on all immunizations, including prophylactic 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 in patients with severe hepatic impairment.

ADVERSE REACTIONS

The most common adverse reactions in RINVOQ clinical trials (≥1%) were: upper respiratory tract infection, nausea, cough, and pyrexia.

RINVOQ Complete Prescription Terms and Conditions

Program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law or by the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any such federal, state, or government-funded healthcare program, patient will no longer be eligible to participate in program. Available to patients between the ages of 18-63 with commercial prescription insurance coverage who meet eligibility criteria. Eligibility: Patients must be diagnosed with moderate to severe rheumatoid arthritis, have a valid prescription for RINVOQ™ and participate in a commercial insurance plan that has denied or not yet made a formulary decision for RINVOQ. Once the patient's insurance plan has made a formulary decision and established a process for reviewing coverage requests for RINVOQ, continued eligibility for the program requires the submission of a Prior Authorization prior to the next scheduled dose and appeal of the coverage denial within 180 days. Program provides RINVOQ at no charge to patients for up to 2 years or until they receive insurance coverage approval, whichever occurs earlier. Offer subject to change or discontinuance without notice. This is not health insurance and program does not guarantee insurance coverage.

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





