RINVOQ® upadacitinib

DOSING AND MONITORING GUIDE

For adult TNFi-IR patients with: moderate to severe rheumatoid arthritis (RA); active psoriatic arthritis (PsA); active ankylosing spondylitis (AS); or active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation[1]

ONE PILL ONCE A DAY

FOUR RHEUMATOLOGY INDICATIONS[1]

RA, PsA, AS AND nr-axSpA

INDICATIONS[1]

RINVOQ is indicated for the treatment of:

- **Moderately to severely active rheumatoid arthritis (RA)** in adults who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
- **Active psoriatic arthritis (PsA)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active ankylosing spondylitis (AS)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active non-radiographic axial spondyloarthritis (nr-axSpA)** with objective signs of inflammation in adults who have had an inadequate response or intolerance to TNF blocker therapy.

Limitations of Use: RINVOQ is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (bDMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

SAFETY CONSIDERATIONS[1]

SERIOUS INFECTIONS

RINVOQ-treated patients are at increased risk of serious bacterial (including tuberculosis [TB]), fungal, viral, and opportunistic infections leading to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

MORTALITY

A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase inhibitor (JAKi) in a study comparing another JAKi with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years with ≥1 CV risk factor.

MALIGNANCIES

Malignancies have occurred in RINVOQ-treated patients. A higher rate of lymphomas and lung cancer (in current or past smokers) was observed with another JAKi when compared with TNF blockers in RA patients.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

A higher rate of CV death, myocardial infarction, and stroke was observed with a JAKi in a study comparing another JAKi with TNF blockers in RA patients ≥50 years with ≥1 CV risk factor. History of smoking increases risk.

THROMBOSIS

Deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. A higher rate of thrombosis was observed with another JAKi when compared with TNF blockers in RA patients.

HYPERSENSITIVITY

RINVOQ is contraindicated in patients with hypersensitivity to RINVOQ or its excipients.

OTHER SERIOUS ADVERSE REACTIONS

Hypersensitivity Reactions, Gastrointestinal Perforations, Laboratory Abnormalities, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on pages 8-9.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf.

abbvie

ONE PILL ONCE A DAY[1]

The recommended dosage of RINVOQ in RA, PsA, AS, and nr-axSpA is 15 mg once daily

Limitations of Use: RINVOQ is not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (bDMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

Instruct patients to:

- Take 1 pill 1 time a day with or without food, and to avoid food or drink containing grapefruit during treatment with RINVOQ.
- Swallow pill whole. Do not split, crush, or chew.
- Notify their healthcare provider if they repeatedly notice intact RINVOQ tablet or fragments in stool or ostomy output.
- Store at 36°F to 77°F (2°C to 25°C) in the original bottle in order to protect from moisture.
- The mean terminal elimination half-life of RINVOQ ranged from 8 to 14 hours.

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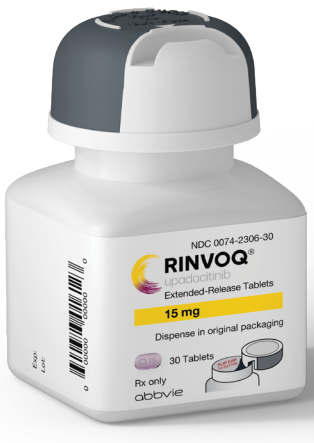
ONE EASY-TO-OPEN BOTTLE[2]

Awarded the Arthritis Foundation Ease of Use Commendation, our innovative bottle cap includes[2]:

- Wide, easy-to-grip texture
- Embedded tool that seamlessly punctures the foil liner to simplify medication access

"I have a lot of trouble puncturing seals now. But this cuts it easily."

– A patient with RA talking about the foil-cutting tool



Arthritis Foundation Ease of Use®

RINVOQ 15 mg extended-release tablets National Drug Code[1]: 0074-2306-30

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LAB MONITORING

Perform lab testing for:

Lab measures	Check lab values
Neutrophils	At baseline and periodically according to routine management thereafter
Lymphocytes	
Hemoglobin	
Liver enzymes	
Lipids[a]	At 12 weeks after initiation and thereafter according to clinical guidelines[a]

[a]Lipids include total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol.

ADDITIONAL DOSING & MONITORING CONSIDERATIONS

MAJOR ADVERSE CARDIOVASCULAR EVENTS[1]

Discontinue RINVOQ in patients that have experienced myocardial infarction or stroke.

THROMBOSIS[1]

Avoid RINVOQ in patients that may be at increased risk for thrombosis. Discontinue RINVOQ and promptly evaluate patients with symptoms of thrombosis.

SERIOUS INFECTIONS[1]

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with RINVOQ.

TUBERCULOSIS (TB)[1]

Test patients for latent and active TB prior to initiation. If positive, treat prior to RINVOQ use. Monitor patients for the development of signs and symptoms of TB, including patients who tested negative for latent TB infection prior to initiating therapy.

VIRAL REACTIVATION[1]

Screening and monitoring for viral hepatitis and herpes zoster reactivation should be performed in accordance with clinical guidelines before starting and during therapy with RINVOQ. If a patient develops herpes zoster, consider temporarily interrupting RINVOQ until the episode resolves.

EMBRYO-FETAL TOXICITY[1]

Based on animal studies, RINVOQ may cause fetal harm when administered to pregnant women. Verify pregnancy status prior to starting treatment. Advise women to use effective contraception during and for 4 weeks after completion of treatment.

VACCINATIONS[1]

Update immunizations, including varicella zoster or prophylactic herpes zoster, according to current immunization guidelines prior to initiation. Avoid use of live vaccines during, or immediately prior to, RINVOQ therapy.

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DOSING CONSIDERATIONS[1]

Initiation and interruption[b]

Lab measures	INTERRUPT TREATMENT OR DO NOT INITIATE IF
Neutrophils	ANC <1000 cells/mm^3
Lymphocytes	ALC <500 cells/mm^3
Hemoglobin	Hb <8 g/dL
Liver enzymes	Elevated liver enzymes & suspected drug-induced liver injury

INTERRUPT IF PATIENT HAS OR DEVELOPS A SERIOUS OR OPPORTUNISTIC INFECTION

[b]Treatment can be initiated or restarted after levels return above specified values, drug-induced liver injury diagnosis is excluded, or infection is controlled.

In RA, PsA, AS, and nr-axSpA:

- **No dose adjustment is required for mild, moderate, or severe renal impairment.[1]**
- **No dose adjustment is required for mild or moderate hepatic impairment.[1]**

RINVOQ is not recommended for patients with:

- **active hepatitis B or hepatitis C**
- **severe hepatic impairment (Child-Pugh C)**

RINVOQ has not been studied in end-stage renal disease (eGFR <15 mL/min/1.73m^2)

HYPERSENSITIVITY[1]

RINVOQ is contraindicated in patients with known hypersensitivity to upadacitinib or any of its excipients. If a clinically significant hypersensitivity reaction occurs, discontinue RINVOQ and institute appropriate therapy.

SAFETY CONSIDERATIONS[1]

SERIOUS INFECTIONS

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OTHER SERIOUS ADVERSE REACTIONS

Hypersensitivity Reactions, Gastrointestinal Perforations, Laboratory Abnormalities, and Embryo-Fetal Toxicity.

ALC=absolute lymphocyte count; ANC=absolute neutrophil count; eGFR=estimated glomerular filtration rate; Hb=hemoglobin.

EXCEPTIONAL PATIENT SUPPORT

Encourage your patients to enroll in RINVOQ Complete:

One-to-One Support

Nurse Ambassadors[a] and Insurance Specialists provide 1-to-1 support to help navigate insurance.

Affordability

Eligible, commercially insured patients may pay as little as $5 per month on their prescription[b]

To get started:
Help your patients enroll in RINVOQ Complete

For any questions, call
1.800.2RINVOQ
(1.800.274.6867)

Enroll today
RINVOQhcp.com/patient-support

[a]Nurse Ambassadors are provided by AbbVie and do not provide medical advice or work under the direction of the prescribing health care professional (HCP). They are trained to direct patients to speak with their HCP about any treatment-related questions, including further referrals.

[b]Eligibility: Available to patients with commercial insurance coverage for RINVOQ® (upadacitinib) who meet eligibility criteria. This co-pay assistance 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. Offer subject to change or termination without notice. Restrictions, including monthly maximums, may apply. This is not health insurance. **For full Terms and Conditions, visit RINVOQSavingsCard.com or call 1.800.2RINVOQ for additional information.** To learn about AbbVie's privacy practices and your privacy choices, visit **https://privacy.abbvie**

References:

1. RINVOQ [package insert]. North Chicago, IL: AbbVie Inc.
2. Fain WB. *Abbvie Child Resistant Special Feature Closure Packaging Evaluation Report of Consumer Product Accessibility for Users with Arthritis.* Atlanta, GA: Intuitive Design Applied Research Institute; 2017.

RINVOQ® COMPLETE

RINVOQ® upadacitinib

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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

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/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 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.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf.

INDICATIONS[1]

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- **Active psoriatic arthritis (PsA)** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
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- **Active non-radiographic axial spondyloarthritis (nr-axSpA)** with objective signs of inflammation in adults who have had an inadequate response or intolerance to TNF blocker therapy.

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See the results

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