RINVOQ™
upadacitinib 15mg tablets

A ONCE-DAILY ORAL THERAPY TAKEN WITH OR WITHOUT MTX[1]

INDICATION[1]

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.

SAFETY CONSIDERATIONS[1]

SERIOUS INFECTIONS

Patients treated with RINVOQ are at increased risk for developing serious infections that may lead to hospitalization or death. These infections include tuberculosis (TB), invasive fungal, bacterial, viral, and other infections due to opportunistic pathogens. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

MALIGNANCY

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

THROMBOSIS

Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions.

OTHER SERIOUS ADVERSE REACTIONS

Patients treated with RINVOQ also may be at risk for other serious adverse reactions, including gastrointestinal perforations, neutropenia, lymphopenia, anemia, lipid elevations, liver enzyme elevations, and embryo-fetal toxicity.

MTX=methotrexate.

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Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Malignancy, and Thrombosis, on page 5.

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

ONE PILL *ONCE* A DAY[1]

RINVOQ™ (upadacitinib) is a **15-mg** extended-release pill that may be used as monotherapy or in combination with methotrexate or other nonbiologic DMARDs.

For MTX-IR patients with moderately to severely active RA:

- Take one pill at about the same time each day
- Ensure pill is taken whole. Do not break, crush, or chew
- Can be taken with or without food
- Store at 36°F to 77°F (2°C to 25°C) in the original bottle in order to protect from moisture

MTX-IR=inadequate response or intolerance to methotrexate; RA=rheumatoid arthritis.

ONE *EASY-TO-OPEN* BOTTLE

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

- 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, I use my finger or a pen to poke it open and then the foil is in the way of the pills. But this cuts it easily. It's much easier than using a pen or my fingers."

– A patient with RA talking about the foil cutting tool

RINVOQ National Drug Code (NDC)[1]: 0074-2306-30

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MONITORING AND TREATMENT CONSIDERATIONS[1]

Lab Monitoring

	Evaluate at baseline	Evaluate according to routine patient management	12 weeks after initiation and thereafter according to clinical guidelines
Neutrophils	✓	✓	
Lymphocytes	✓	✓	
Hemoglobin	✓	✓	
Lipids[a]			✓
Liver enzymes	✓	✓	

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

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

RINVOQ is not recommended for use in patients with severe hepatic impairment.[1]

Initiation and Interruption[b]

LAB MEASURE	DO NOT INITIATE TREATMENT OR INTERRUPT
Neutrophils	If ANC<1000 cells/mm^3[,b]
Lymphocytes	If ALC<500 cells/mm^3[,b]
Hemoglobin	If Hb<8 g/dL[b]
Liver enzymes	If liver enzyme elevations and a drug-induced liver injury is suspected

INTERRUPT IF PATIENT 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.

ALC=absolute lymphocyte count; ANC=absolute neutrophil count; Hb=hemoglobin.

Serious Infections[1]
Closely monitor patients for the development of signs and symptoms of infection during and after treatment with RINVOQ.

Tuberculosis[1]
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 for viral hepatitis and monitoring for reactivation should be performed in accordance with clinical guidelines before starting and during therapy with RINVOQ.

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.

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ONE EXCEPTIONAL PATIENT EXPERIENCE

RINVOQ™ COMPLETE

RINVOQ Complete will provide your patients support to fit RINVOQ into their life, so they can start and stay on track with their prescribed treatment with a once-daily 15-mg pill.

NURSE AMBASSADORS[a]

- Provide 1:1 support to help meet the unique needs of each individual patient

ACCESS SPECIALISTS

- Resource with expertise on Medicare and commercial plans at a national, local, and program level so that they can educate on potential options to consider based on each patient's unique financial situation

ACCESS SAVINGS

- RINVOQ Complete may help eligible commercially insured patients experiencing initial coverage delays or denials access their prescribed therapy at no charge while coverage is established. Eligibility criteria apply[b]
- With the RINVOQ Complete Savings Card, your eligible commercially insured patients may pay as little as $5 per month[c]

TO GET STARTED:
Enroll your patients in RINVOQ Complete

Complete the single enrollment and prescription form and RINVOQ Complete will follow up with you on eligibility and any next steps for you to complete.

Download the Complete enrollment and prescription form at **RinvoqHCP.com/form**

For any questions, call
1.800.2RINVOQ
(1.800.274.6867).

[a]Ambassadors do not provide medical advice and are trained to direct patients to speak with their healthcare professional about any treatment-related questions, including further referrals.

[b]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.

[c]Terms and Conditions apply. This benefit covers RINVOQ™ (upadacitinib) alone or for RINVOQ plus one of the following medications: methotrexate, leflunomide (Arava®), or hydroxychloroquine (Plaquenil®). Eligibility: Available to patients with commercial prescription insurance coverage for RINVOQ who meet eligibility criteria. 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 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 able to use the RINVOQ Complete Savings Card and patient must call RINVOQ Complete at 1.800.2RINVOQ to stop participation. Patients residing in or receiving treatment in certain states may not be eligible. Patients may not seek reimbursement for value received from the RINVOQ Complete program from any third-party payers. Offer subject to change or discontinuance without notice. Restrictions, including monthly maximums, may apply. This is not health insurance.

References:
1. RINVOQ [package insert]. North Chicago, IL: AbbVie Inc; 2019. **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.

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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 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

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 clinical studies. 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 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.

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