STARTING PATIENTS ON

RINVOQ™
upadacitinib

Indication[1]
RINVOQ is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). RINVOQ may be used as monotherapy or in combination with methotrexate.

▼ This product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

DOSING AND ADMINISTRATION

One dose, one tablet, once a day[1]

- Recommended dose is one 15-mg tablet once a day, with or without food
- Tablets should be swallowed whole with water, and should not be split, crushed, or chewed
- RINVOQ™ may be taken at any time of day; patients may find it easier to take RINVOQ at the same time every day to help them remember to take it

What to do about missed doses[1]

- Patients should take RINVOQ as soon as they remember the missed dose
- Patients who forget a dose for an entire day should skip that dose and take only a single dose as usual the following day
- Patients should not take a double dose to make up for a forgotten tablet

Please refer to the Summary of Product Characteristics for complete prescribing information.

Dosing in special populations[1]

- No dose adjustment is required in patients aged 65 years and older. There are limited data in patients aged 75 years and older.
- No dose adjustment is required in patients with mild or moderate renal impairment. There are limited data on the use of RINVOQ in subjects with severe renal impairment. RINVOQ should be used with caution in patients with severe renal impairment. The use of RINVOQ has not been studied in subjects with end-stage renal disease.
- No dose adjustment is required in patients with mild (Child Pugh A) or moderate (Child Pugh B) hepatic impairment. RINVOQ should not be used in patients with severe (Child Pugh C) hepatic impairment.
- The safety and efficacy of RINVOQ in children and adolescents aged 0 to less than 18 years have not yet been established. No data are available.

TREATMENT CONSIDERATIONS

Treatment with RINVOQ should not be initiated in patients with any of the following:

- Absolute neutrophil count <1,000 cells/mm^3*
- Absolute lymphocyte count <500 cells/mm^3*
- Hemoglobin <8 g/dL*

*Treatment may be initiated or restarted after levels return above specified values.

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MONITORING GUIDANCE

Laboratory measures and monitoring guidance[1]

LABORATORY MEASURE	ACTION	MONITORING GUIDANCE
Absolute neutrophil count (ANC)	Treatment should be interrupted if ANC is <1,000 cells/mm^3 and may be restarted once ANC returns above this value	Evaluate at baseline and thereafter according to routine patient management
Absolute lymphocyte count (ALC)	Treatment should be interrupted if ALC is <500 cells/mm^3 and may be restarted once ALC returns above this value	
Hemoglobin (Hb)	Treatment should be interrupted if Hb is <8 g/dL and may be restarted once Hb returns above this value	
Hepatic transaminases	Treatment should be temporarily interrupted if drug-induced liver injury is suspected	
Lipids	Patients should be managed according to international clinical guidelines for hyperlipidemia	12 weeks after initiation of treatment and thereafter according to international clinical guidelines for hyperlipidemia

Serious infections: RINVOQ should not be initiated in patients with an active, serious infection, including localized infections. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with RINVOQ. If a patient develops a serious or opportunistic infection, RINVOQ should be interrupted.

Tuberculosis (TB): Patients should be screened for TB before starting RINVOQ. RINVOQ should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of RINVOQ in patients with previously untreated latent TB or in patients with risk factors for TB infection. 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: Screening for viral hepatitis and monitoring for reactivation should be performed before starting and during therapy with RINVOQ. If a patient develops herpes zoster, consider interruption of RINVOQ therapy until the episode resolves. If hepatitis B virus DNA is detected while receiving RINVOQ, a liver specialist should be consulted.

Venous thromboembolism: RINVOQ should be used with caution in patients at high risk for deep venous thrombosis (DVT)/pulmonary embolism (PE). Risk factors that should be considered in determining the patient's risk for DVT/PE include older age, obesity, a medical history of DVT/PE, patients undergoing major surgery, and prolonged immobilization. If clinical features of DVT/PE occur, RINVOQ treatment should be discontinued and patients should be evaluated promptly, followed by appropriate treatment.

Nonmelamona skin cancer: Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

ADDITIONAL IMPORTANT INFORMATION

Vaccinations[1]

Use of live, attenuated vaccines during or immediately prior to RINVOQ treatment is not recommended. Prior to initiating RINVOQ, it is recommended that patients be brought up to date with all immunizations, including prophylactic zoster vaccinations, in agreement with current immunization guidelines.

Contraception[1]

Women of childbearing potential should use effective contraception during treatment and for 4 weeks following the final dose of RINVOQ. If a patient becomes pregnant while taking RINVOQ, they should be informed of the potential risk to the fetus.

Pregnancy and lactation[1]

RINVOQ is contraindicated during pregnancy. Studies in animals have shown reproductive toxicity. **RINVOQ should not be used during breastfeeding,** as it is unknown whether RINVOQ or its metabolites are excreted in human milk. A decision must be made whether to discontinue breastfeeding or to discontinue RINVOQ treatment, taking into account the benefit of breastfeeding for the child and the benefit of treatment for the woman.

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SAFETY INFORMATION[1]

The use of RINVOQ is contraindicated in patients:[1]

- Who are hypersensitive to the active substance or to any of the excipients
- With active tuberculosis (TB) or active serious infections
- With severe hepatic impairment
- Who are pregnant

Important Safety Information[1]

RINVOQ is contraindicated in patients hypersensitive to the active substance or to any of the excipients, in patients with active tuberculosis (TB) or active serious infections, in patients with severe hepatic impairment, and during pregnancy.

Use in combination with other potent immunosuppressants is not recommended.

Serious and sometimes fatal infections have been reported in patients receiving upadacitinib. The most frequent serious infections reported included pneumonia and cellulitis. Cases of bacterial meningitis have been reported. Among opportunistic infections, TB, multidermatomal herpes zoster, oral/esophageal candidiasis, and cryptococcosis have been reported with upadacitinib. Prior to initiating upadacitinib, consider the risks and benefits of treatment in patients with chronic or recurrent infection or with a history of a serious or opportunistic infection, in patients who have been exposed to TB or have resided or traveled in areas of endemic TB or endemic mycoses, and in patients with underlying conditions that may predispose them to infection. Upadacitinib therapy should be interrupted if a patient develops a serious or opportunistic infection. As there is a higher incidence of infections in patients ≥75 years of age, caution should be used when treating this population.

Patients should be screened for TB before starting upadacitinib therapy. Anti-TB therapy should be considered prior to initiation of upadacitinib in patients with previously untreated latent TB or in patients with risk factors for TB infection.

Viral reactivation, including cases of herpes zoster, were reported in clinical studies. Consider interruption of therapy if a patient develops herpes zoster until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed before starting and during therapy with upadacitinib.

The use of live, attenuated vaccines during or immediately prior to therapy is not recommended. It is recommended that patients be brought up to date with all immunizations, including prophylactic zoster vaccinations, prior to initiating upadacitinib, in agreement with current immunization guidelines.

The risk of malignancies, including lymphoma is increased in patients with rheumatoid arthritis (RA). Immunomodulatory medicinal products may increase the risk of malignancies, including lymphoma. The clinical data are currently limited and long-term studies are ongoing. Malignancies, including nonmelanoma skin cancer (NMSC), have been reported in patients treated with upadacitinib. Consider the risks and benefits of upadacitinib treatment prior to initiating therapy in patients with a known malignancy other than a successfully treated NMSC or when considering continuing upadacitinib therapy in patients who develop a malignancy. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

Absolute neutrophil count <1000 cells/mm^3, absolute lymphocyte count <500 cells/mm^3, or hemoglobin levels <8 g/dL were reported in ≤1% of patients in clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with these hematological abnormalities observed during routine patient management.

RA patients have an increased risk for cardiovascular disorders. Patients treated with upadacitinib should have risk factors (e.g., hypertension, hyperlipidemia) managed as part of usual standard of care.

Upadacitinib treatment was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined.

Treatment with upadacitinib was associated with an increased incidence of liver enzyme elevation compared to placebo. If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, upadacitinib therapy should be interrupted until this diagnosis is excluded.

Events of deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors, including upadacitinib. Upadacitinib should be used with caution in patients at high risk for DVT/PE. Risk factors that should be considered in determining the patient's risk for DVT/PE include older age, obesity, a medical history of DVT/PE, patients undergoing major surgery, and prolonged immobilization. If clinical features of DVT/PE occur, upadacitinib treatment should be discontinued and patients should be evaluated promptly, followed by appropriate treatment.

The most commonly reported adverse drug reactions are upper respiratory tract infections (13.5%), nausea (3.5%), increased blood creatine phosphokinase (2.5%), and cough (2.2%). The most common serious adverse reactions were serious infections.

Please see the SmPC for complete prescribing information.

References: 1. RINVOQ [Summary of Product Characteristics]. AbbVie Deutschland GmbH & Co. KG; [MM,YYYY]. **2.** European Medicines Agency. RINVOQ medicine overview. https://www.ema.europa.eu/en/documents/overview/rinvoq-epar-medicine-overview_en.pdf. Updated XXXXXX. Accessed XXXXXX.

INFORMATION ABOUT STORAGE

Storage[1]

- RINVOQ tablets are provided in aluminum blisters or in bottles
- Patients should not use RINVOQ after the expiry date stated on the blister label and carton after "EXP"
- RINVOQ should be stored in the original blister pack or bottle with the lid tightly closed to protect from moisture

Please refer to the Summary of Product Characteristics for complete prescribing information.

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A NEW RA TREATMENT

- A once-daily selective and reversible JAK inhibitor[1]
- For adult patients with moderate to severe active RA and an inadequate response to or intolerance to one or more DMARDs[1]
- RINVOQ's safety has been established across 5 robust Phase 3 clinical trials involving more than 4,000 patients and more than 5,000 patient-years of exposure[2]

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