RINVOQ is indicated for the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations 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

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.

Mortality: A higher rate of all-cause mortality, including sudden cardiovascular (CV) death, was observed with a Janus kinase (JAK) inhibitor in a study comparing another JAK inhibitor with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA) patients ≥50 years of age with at least one CV risk factor. Current or past smokers are at additional increased risk.

Thrombosis: Thrombosis, including 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 JAK inhibitor when compared with TNF blockers in RA patients.

Hypersensitivity: RINVOQ is contraindicated in patients with known hypersensitivity to upadacitinib or any of its excipients.

Other Serious Adverse Reactions: Hypersensitivity Reactions (anaphylaxis and angioedema), Gastrointestinal Perforations, Laboratory Abnormalities (neutropenia, lymphopenia, anemia, lipid elevations, liver enzyme elevations), and Embryo-Fetal Toxicity.
RINVOQ is indicated for TNFi-IR patients.1 PRIMARY ENDPOINT AT WEEK 14 (VS 18.2% PLACEBO, P<0.0001)1,2

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections, Mortality, Malignancies, Major Adverse Cardiovascular Events, and Thrombosis, on page 5.

All other comparisons were not adjusted for multiplicity; therefore, statistical significance has not been established.

SELECT-AXIS 2 (bDMARD-IR): ASAS40 Response2

RINVOQ is indicated for TNFi-IR patients1

DATA LIMITATIONS: Data labeled as primary and ranked secondary endpoints at Week 14 were multiplicity-controlled. All other comparisons were not adjusted for multiplicity; therefore, statistical significance has not been established.

SAFETY CONSIDERATIONS1

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.

Mortality: A higher rate of all-cause mortality, including cardiovascular (CV) death, was observed with a JAK inhibitor in a study comparing another JAK inhibitor with TNF blockers in RA patients ≥50 years of age with at least one CV risk factor. Current or past smokers are at additional increased risk.

Malignancies: Lymphoma and other malignancies have been observed in RINVOQ-treated patients. A higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]), lymphomas, and lung cancer (in current or past smokers) was observed with another JAK inhibitor when compared with TNF blockers in RA patients. Patients who are current or past smokers are at additional increased risk.

Hypersensitivity: RINVOQ is contraindicated in patients with known hypersensitivity to upadacitinib or any of its excipients.

Other Serious Adverse Reactions: Hypersensitivity reactions (anaphylaxis and angioedema), Gastrointestinal Perforations, Laboratory Abnormalities (neutropenia, lymphopenia, anemia, lipid elevations, liver enzyme elevations), and Embryo-Fetal Toxicity.

Please see important additional safety information, including boxed warning on serious infections, mortality, malignancies, major adverse cardiovascular events, and thrombosis, on page 5.

Please see accompanying full prescribing information, including boxed warning, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf.

AS Disease Activity States3,4

Change in Baseline
ASDAS-CRP Score at Week 14
(Not a ranked secondary endpoint)

RINVOQ patients: -1.52
Placebo patients: -0.49

Change in Baseline
ASDAS-CRP Score at Week 14

RINVOQ: 1.9
Placebo: 0.7

Low Disease Activity

Inactive Disease

ASDAS-CRP Low Disease Activity Achieved

44% of bDMARD-IR patients achieved ASDAS-CRP LDA vs 10% placebo at Week 142*

ASDAS-CRP Low Disease Activity (LDA)3

ASDAS-CRP Low Disease Activity Achieved

SELECT-AXIS 2 (bDMARD-IR): ASDAS-CRP Low Disease Activity (LDA)2
RINVOQ IS A ONCE-DAILY ORAL THERAPY1

14-week double-blind, parallel-group, placebo-controlled phase 3 study of 420 patients with active AS who had an intolerance or inadequate response to at least 2 NSAIDs and 1 or 2 bDMARDs. Patients were randomized to receive RINVOQ 15 mg once daily or placebo. Patients could continue background NSAIDs. The primary endpoint was the proportion of patients who achieved an ASAS40 response at Week 14.

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 immunosuppressant agents, such as methotrexate or corticosteroids. If a serious infection develops, interrupt RINVOQ; if the infection is severe, discontinue RINVOQ.

Reported infections include:
- Active tuberculosis (TB), which may manifest with pulmonary or extrapulmonary disease. Test patients for latent TB before RINVOQ use and during therapy. Consider treating latent TB infection prior to initiating RINVOQ.
- Infections caused by opportunistic pathogens, including oropharyngeal candidiasis 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 withdrawal of RINVOQ, including for possible breakthrough infection at TB in patients who tested negative for latent TB infection prior to initiating therapy.

MONITORING
- Lymphoma and other malignancies have been observed in patients treated with RINVOQ.
- In a large, randomized, postmarketing safety study comparing another Janus kinase (JAK) inhibitor with tumor necrosis factor (TNF) blockers in rheumatoid arthritis (RA), patients 65 years old with at least one cardiovascular (CV) risk factor (history of smoking, hypertension, diabetes mellitus, hyperlipidemia, or stroke) had a significantly higher incidence of MALT lymphoma (which may be presymptomatic) observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating therapy with RINVOQ.

CONTRAINDICATIONS
- RINVOQ is contraindicated in patients with a known hypersensitivity to RINVOQ.
- RINVOQ is contraindicated in patients with active, severe, or uncontrolled infections.

WARNING
- Lymphoma and other malignancies have been observed in patients treated with RINVOQ.
- Hypersensitivity reactions, including 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.

THROMBOSIS
A higher rate of all-cause mortality, including sudden CV death, was observed with RINVOQ compared to placebo. The absolute risk difference was 4.2[ deaths per 1000 patient years], with a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) was observed with RINVOQ compared to placebo. ACE therapy was associated with an increased risk. Discontinue RINVOQ in patients that have experienced a CV death, myocardial infarction, stroke, or CV hospitalization.

Hyperlipidemia
Hyperlipidemia
Liver enzyme elevations were observed during routine patient management and drug-induced liver injury is recommended to identify potential cases of drug-induced liver injury. Infections due to opportunistic pathogens, including oropharyngeal candidiasis and pneumocystosis.

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

MAJOR ADVERSE CARDIOVASCULAR EVENTS
In a large, randomized, postmarketing safety study comparing another JAK inhibitor with TNF blockers in RA patients 65 years old with at least one CV risk factor, a higher rate of MALT lymphoma (which may be presymptomatic) observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating therapy with RINVOQ.

HYPERSENSITIVITY
- RINVOQ is contraindicated in patients with known hypersensitivity toesdacl or any of its excipients. Serious hypersensitivity reactions, including anaphylaxis and angioedema, were reported in patients treated with RINVOQ in clinical trials.

ADVERSE REACTIONS
- In a large, randomized, postmarketing safety 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 MALT lymphoma (which may be presymptomatic) observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating therapy with RINVOQ.

ADVERSE REACTIONS
- In a large, randomized, postmarketing safety 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 MALT lymphoma (which may be presymptomatic) observed with the JAK inhibitor. Consider the benefits and risks for the individual patient prior to initiating therapy with RINVOQ.

LASER THERAPY
- 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 6 weeks after the last dose. Urge women who are pregnant to avoid breastfeeding.

HEPATIC IMPAIRMENT
RINVOQ is not recommended for use in patients with severe hepatic impairment.

References
CONFIDENCE IN ACCESS

>9 OUT OF 10 COMMERCIAL PATIENTS HAVE ACCESS TO RINVOQ FOR AS

Access is as of April 2022 and available through commercial insurance, or through RINVOQ Complete if coverage is denied**

Encourage your patients to enroll in RINVOQ® COMPLETE

Affordability: Eligible commercially insured patients may pay as little as $5 per month†

Access: No charge for eligible patients experiencing initial insurance delay or denial for up to 24 months*

Exceptional 1:1 patient support when your patients enroll in RINVOQ Complete

SAFETY CONSIDERATIONS1

**Commercial insurance coverage varies by type and plan. 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 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 Medicare, 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.

†Eligibility: Available to patients with commercial insurance coverage for RINVOQ 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. To learn about AbbVie’s privacy practices and your privacy choices, visit www.abbvie.com/privacy.html

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