RINVOQ® (upadacitinib) PRODUCT FACT SHEET

Not actual size.

INDICATIONS[1]

RINVOQ is indicated for the treatment of:

- **Moderately to severely active rheumatoid arthritis** in adults who have had an inadequate response or intolerance to one or more TNF blockers.
- **Active psoriatic arthritis** in adults 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.

- **Refractory, moderate to severe atopic dermatitis** in adults and pediatric patients 12 years of age and older whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.

Limitations of Use: RINVOQ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

PRODUCT OVERVIEW

DOSAGE AND ADMINISTRATION[1]	**For RA/PsA:** The recommended oral dose is 15 mg once daily with or without food. **For AD:** For adults <65 years of age and pediatric patients 12 years of age and older weighing at least 40 kg: • Initiate treatment with 15 mg once daily • If an adequate response is not achieved, consider increasing the dosage to 30 mg once daily • Discontinue RINVOQ if an adequate response is not achieved with the 30 mg dose • Use the lowest effective dose needed to maintain response For patients ≥65 years of age, patients with severe renal impairment, and patients receiving strong CYP3A4 inhibitors: • The recommended dosage is 15 mg once daily
PACKAGING[1]	30 tablets in a bottle Description: • 15 mg: purple, biconvex oblong, with dimensions of 14 x 8 mm, and debossed with 'a15' on one side • 30 mg: red, biconvex oblong, with dimensions of 14 x 8 mm, and debossed with 'a30' on one side
STORAGE AND HANDLING[1]	Store at 2˚C to 25˚C (36˚F to 77˚F). Store in the original bottle in order to protect from moisture.

AD, atopic dermatitis; CYP3A4, cytochrome P450 3A4; DMARD, disease-modifying antirheumatic drug; JAK, Janus kinase; PsA, psoriatic arthritis; RA, rheumatoid arthritis; TNF, tumor necrosis factor.

RINVOQ 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.

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.

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.

Major Adverse Cardiovascular Events: A higher rate of CV death, myocardial infarction, and stroke 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.

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.

Please see additional Important Safety Information, including BOXED WARNING on SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS on pages 3 and 4. Please see accompanying full Prescribing Information, including BOXED WARNING, or visit https://www.rxabbvie.com/pdf/rinvoq_pi.pdf

RINVOQ® upadacitinib