

Generic Name:

Upadacitinib

Trade Name:

Rinvoq

Company:

AbbVie

Notes:

On August 16, AbbVie [announced](#) FDA approval of upadacitinib, a 15-mg, once-daily oral Janus kinase (JAK) inhibitor, for treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate (MTX-IR).

Approval was supported by data from the SELECT program, one of the largest registrational Phase III programs in RA, with approximately 4,400 patients evaluated across all treatment arms in five studies. The studies include assessments of efficacy, safety, and tolerability across a variety of RA patients, including those who failed or were intolerant to biologic disease-modifying antirheumatic drugs and who were naive or inadequate responders to methotrexate. Upadacitinib is not indicated for methotrexate-naive patients.

Across the SELECT Phase III studies, upadacitinib met all primary and ranked secondary endpoints.

The recommended dosage is 15 mg taken once a day with or without food.

The most common adverse effects include upper respiratory tract infections (common cold, sinus infections), nausea, cough, and pyrexia. Patients treated with the drug are at increased risk for developing serious infections that may lead to hospitalization or death. These infections include tuberculosis and invasive fungal, bacterial, viral, and other infections caused by opportunistic pathogens. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Lymphoma and other malignancies have been observed in patients treated with upadacitinib. Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with JAK inhibitors used to treat inflammatory conditions. Patients treated also may be at risk for other serious adverse reactions, including GI perforations, neutropenia, lymphopenia, anemia, lipid elevations, liver enzyme elevations, and embryo-fetal toxicity.

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