Rinvoq (upadacitinib)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Rinvoq
- **Generic name:** Upadacitinib
- **Pharmacological class:** Janus kinase (JAK) inhibitor
- **Strength and Formulation:** 15mg; extended-release tablets
- **Manufacturer:** AbbVie
- **How supplied:** Bottles—30
- **Legal Classification:** Rx

Rinvoq


NDC 0074-2306-30
RINVOQ™
upadacitinib
Extended-Release Tablets
15 mg
Dispense in original packaging
30 Tablets
Rx only
abbvie
FLIP CAP TO CUT FOIL

Indication

- Moderately to severely active **rheumatoid arthritis** (RA) in adults who have had an inadequate response or intolerance to methotrexate (MTX)

Dosage & Administration

- Swallow whole
- ≥18yrs: 15mg once daily
- May be used as monotherapy or in combination with MTX or other nonbiologic DMARDs
- Dose interruption: see full labeling

Considerations for Special Populations

- **Pregnancy:** may cause fetal harm based on animal studies; advise females of reproductive potential of the potential risk to a fetus and to use effective contraception
- **Nursing mothers**: not recommended (during and for 6 days after the last dose)
- **Pediatric**: safety and efficacy not established in children and adolescents aged 0 to 18 years
- **Geriatric:** No overall differences in safety or efficacy were observed between these patients and younger patients
- **Renal impairment:** not studied in patients with end stage renal disease
- **Hepatic impairment:** not recommended for use in patients with severe impairment

Boxed Warnings

- **Serious infections**
  - Reported infections include: active tuberculosis, invasive fungal infections, bacterial, viral, and other infections due to opportunistic pathogens
  - If serious infection develops, interrupt treatment until the infection is controlled
- **Malignancy**
  - Lymphoma and other malignancies have been observed in treated patients
- **Thrombosis**
  - DVT, PE, and arterial thrombosis have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions

Warnings/Precautions

- Increased risk of **serious infections** (eg, TB, bacterial, viral, invasive fungal, or other opportunistic pathogens)
- Avoid in active, serious, or localized infections
- Consider the risks/benefits in chronic, recurrent, or history of serious or opportunistic infections
- Travel to, or residence in, areas with endemic TB or mycoses
- Conditions that predispose to infection
- Test/treat latent TB infection prior to and per applicable guidelines during therapy

Warnings/Precautions

- Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of herpes virus or hepatitis occurs; interrupt treatment if serious or opportunistic infection
- Screen for viral hepatitis before starting and during therapy
- Thrombosis risk
- Known malignancy
- GI perforation risk (eg, history of diverticulitis)
- Perform periodic skin exam in those with skin cancer risk

Warnings/Precautions

- Update immunization based on current guidelines prior to initiating therapy
- Do not initiate therapy if lymphocytes <500cells/mm^3, ANC <1000cells/mm^3, or hemoglobin <8g/dL
- Monitor lymphocytes, neutrophils, and hemoglobin at baseline, then periodically thereafter
- Routinely monitor liver enzymes; interrupt therapy if ALT/AST elevated and drug-induced liver injury is suspected
- Monitor lipids 12 weeks following initiation and manage hyperlipidemia

Warnings/Precautions

- Severe hepatic impairment: not recommended
- Elderly
- Embryo-fetal toxicity
- Advise females of reproductive potential to use effective contraception during and for 4 weeks after the last dose
- Pregnancy: exclude status prior to initiation
- Nursing mothers: not recommended (during and for 6 days after the last dose)

Interactions

- Concomitant live vaccines, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine): not recommended
- **Potentiated by** strong CYP3A4 inhibitors (eg, ketoconazole); caution
- **Antagonized by** strong CYP3A4 inducers (eg, rifampin); not recommended
- Caution with NSAIDs

Adverse Reactions

- **Most common** (≥1%): upper respiratory tract infections, nausea, cough, pyrexia
- **Others**: serious or opportunistic infections, TB, GI perforations, malignancies (eg, lymphoma), thrombosis (evaluate and treat if occurs), cytopenias, liver enzyme or lipid elevations, non-melanoma skin cancer

Mechanism of Action

- Upadacitinib modulates the signaling pathway at the point of JAKs, thus preventing the phosphorylation and activation of Signal Transducers and Activators of Transcription (STATs), which are modulators of intracellular activity including gene expression

Clinical Trials

- The efficacy and safety of Rinvoq were assessed in five phase 3 randomized, double-blind, multicenter trials involving approximately 4400 patients with moderately to severely active RA, including those who failed or were intolerant to biologic DMARDs and who were naive or inadequate responders to methotrexate (MTX)

Clinical Trials

- Results from **Study RA-I** showed that 52% of methotrexate-naive patients treated with Rinvoq achieved ACR50 (primary end point) vs 28% treated with MTX at Week 12
- In **Study RA-II**, 68% of patients who were inadequate responders to methotrexate (MTX-IR) treated with Rinvoq achieved ACR20 (primary end point) vs 41% on continued MTX at Week 14
- **Study RA-III** showed that 64% of patients with inadequate response to conventional DMARDs (cDMARDs) treated with Rinvoq plus cDMARDs achieved ACR20 vs 36% with placebo plus cDMARDs at Week 12

Clinical Trials

- In **Study RA-IV**, 71% of MTX-IR patients treated with Rinvoq plus MTX achieved ACR20 vs 36% for placebo plus MTX at Week 12
- **Study RA-V** showed that 65% of patients who had an inadequate response or intolerance to biologic DMARDs treated with Rinvoq plus cDMARDs achieved ACR20 vs 28% treated with placebo plus cDMARDs at Week 12
- A higher proportion of patients treated with Rinvoq alone or in combination with cDMARDs achieved **clinical remission** (as assessed by DAS28-CRP<2.6) compared with MTX or placebo in 2 of the studies (RA-I & -IV)

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/rinvoq/