Olumiant (baricitinib)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Olumiant
- **Generic name:** Baricitinib
- **Pharmacological class:** Janus kinase (JAK) inhibitor
- **Strength and Formulation:** 2mg; tabs
- **Manufacturer:** Eli Lilly
- **How supplied:** Tabs—30
- **Legal Classification:** Rx

Indications

- Moderately-to-severely active **rheumatoid arthritis (RA)** in adults who have had an inadequate response to 1 or more tumor necrosis factor (TNF) antagonists

Limitations of Use

- **Not recommended** for use with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine)

Olumiant

Dosage & Administration

- Take with or without food
- 2mg once daily
- May be used as monotherapy or in combination with methotrexate or other DMARDs
- Dose modifications: see full labeling

Considerations for Special Populations

- **Pregnancy:** Insufficient data to inform drug-associated risk
- **Nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Elderly:** Monitor renal function
- **Renal impairment:** eGFR <60mL/min/1.73 m^2: not recommended
- **Hepatic impairment:** Severe: not recommended

Warnings/Precautions

- Increased risk of serious or fatal **infections** (eg, TB, bacterial, viral, invasive fungal, or other opportunistic pathogens)
- **Avoid** in active, serious, or localized infections
- Chronic, recurrent, or history of serious or opportunistic infections

Warnings/Precautions

- 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
- **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, or sepsis develops

Warnings/Precautions

- Known malignancy
- GI perforations risk (eg, history of diverticulitis)
- Thrombosis risk
- Perform periodic skin exam in those with skin cancer risk
- Update immunization based on current guidelines prior to initiating therapy
- Do not initiate therapy if lymphocytes <500 cells/mm^3, ANC <1000 cells/mm^3, or hemoglobin <8g/dL

Warnings/Precautions

- 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

Interactions

- Concomitant live vaccines, strong OAT3 inhibitors (eg, probenecid): **not recommended**

Adverse Reactions

- Upper respiratory tract infections
- Nausea
- Herpes simplex
- Herpes zoster
- Other serious or opportunistic infections
- Tuberculosis
- Malignancies
- Cytopenias
- Liver enzyme or lipid elevations
- Non-melanoma skin cancer
- Thrombosis

Mechanism of Action

- **Baricitinib** is a JAK inhibitor that modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of the STATs (Signal Transducers and Activators of Transcription)

Clinical Studies

- **Olumiant** was studied in 2 confirmatory Phase 3, randomized, double-blind, multicenter studies (Study III and Study IV) in patients with rheumatoid arthritis aged >18 years

Clinical Studies

- **Study III** (N=684) was a 24-week trial that included patients who had an inadequate response or intolerance to conventional DMARDs (cDMARDs)
- **Study IV** (N=527) was a 24-week trial that included patients who had an inadequate response or intolerance to ≥1 TNF inhibitors with or without other biologic DMARDs (TNFi-IR)

Clinical Studies

- Patients were randomized to Olumiant 2mg or 4mg once daily or placebo added to existing cDMARD treatment
- The **primary endpoint** was the proportion of patients who achieved ACR20 response at week 12

Clinical Studies

- ACR20 response in **Study III**:
  - Week 12: 66% Olumiant 2mg vs 39% placebo
  - Week 24: 61% vs 42%
- ACR20 response in **Study IV**:
  - Week 12: 49% Olumiant 2mg vs 27% placebo
  - Week 24: 45% vs 27%

Clinical Studies

- DAS28-CRP <2.6 in **Study III**:
  - Week 12: 26% Olumiant 2mg vs 9% placebo
  - Week 24: 31% vs 11%
- DAS28-CRP <2.6 in **Study IV**:
  - Week 12: 11% Olumiant 2mg vs 4% placebo
  - Week 24: 11% vs 6%

Clinical Studies

- In both studies, Olumiant-treated patients had higher rates of ACR response and DAS28-CRP <2.6 vs placebo-treated patients at week 12
- In Study IV, higher ACR20 response rates were seen as early as 1 week with Olumiant 2mg vs placebo

Clinical Studies

- Patients receiving Olumiant 2mg had greater improvement from baseline in physical functioning vs placebo at week 24

- For more clinical data info, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/olumiant/drug/34843