Olumiant (baricitinib)
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 m²: not recommended
- **Hepatic impairment**: Severe: not recommended
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 $<8$g/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
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).
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