ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

Association of Rheumatology Professionals
The Interprofessional Division of the American College of Rheumatology

Baricitinib (Olumiant®)

Baricitinib (Olumiant) is a Janus Kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. JAKs inhibitors prevent the phosphorylation and activation of Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. JAK enzymes transmit cytokine signaling through pairing of JAKs, with baricitinib inhibiting in vitro activities of JAK1, JAK2, and TYK2 relative to JAK3.

Resources from Manufacturer

Patient Medication Guide
Full Prescribing Information
Olumiant Co-pay Assistance Program
Lilly Cares Patient Assistance Program

Indications and Dosing in Rheumatology

Baricitinib is indicated for:

- Adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more TNF blockers

Dosing:

- 2 mg by mouth once daily
- Baricitinib may be used as monotherapy or in combination with nonbiologic DMARDs
- Baricitinib is not recommended for use in patients with severe hepatic impairment
- The recommended dosing in moderate renal impairment (30 - <60 mL/min/1.73 m2) is 1 mg once daily
  - ❑ Use not recommended in severe renal impairment (30 mL/min/1.73 m2) or dialysis
- Adjust dosing for drug interactions with strong OAT3 inhibitors (e.g. probenecid)
- Interrupt dosing if laboratory abnormalities occur in absolute neutrophil count (ANC), absolute lymphocyte count (ALC), or hemoglobin:

	Threshold	Recommendation
ANC	<1,000 cells/μL	Interrupt treatment until ≥1,000 cells/ μL
ALC	<500 cells/ μL	Interrupt treatment until ≥500 cells/ μL
Hemoglobin	< 8 g/dL	Interrupt treatment until ≥8 g/dL

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Contraindications

None

Black Box Warnings

- Serious Infections–Avoid use during an active serious infection, including localized infection.
  - Tuberculosis–Evaluate and test for latent or active infection prior to and during administration of baricitinib.
- Mortality–Patients 50 years and older with at least one cardiovascular risk factor treated with JAK inhibitor had a higher observed rate of all-cause mortality.
- Malignancy–Lymphomas and solid cancers were observed in clinical trials.
- Major adverse cardiovascular events–Patients 50 years and older with at least one cardiovascular risk factor treated with JAK inhibitor had a higher rate of major adverse cardiovascular events (MACE) defined as cardiovascular death, non-fatal myocardial infarction (MI), and non-fatal stroke.
- Thrombosis–Pulmonary embolism (PE), deep venous thrombosis (DVT), and arterial thrombosis have occurred in patients treated with JAK inhibitors.

Warnings and Precautions

- Gastrointestinal perforation–Use with caution in patients who may be at increased risk.
- Hypersensitivity–Discontinue if serious hypersensitivity reaction occurs.
- Laboratory abnormalities–Monitor for changes in lymphocytes, neutrophils, hemoglobin, liver enzymes, and lipids.
- Live vaccines–Avoid use.

Adverse Reactions

Most common adverse reactions (≥ 1%):

- Upper respiratory infections
- Nausea
- Herpes simplex and herpes zoster

Medication Strength and Preparations

- Tablets: 1 mg, 2 mg, 4 mg

Medication Administration and Storage

- Store in original carton to protect from light
- Store at room temperature, 20°C to 25°C (68°F to 77°F)

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Oral Administration

- Take by mouth with or without food.
- For patients who are unable to swallow whole tablets, place dose in a container with approximately 10 mL (5 mL minimum) of room temperature water, disperse by gently swirling the tablets, then take orally immediately. Rinse the container with an additional 10 mL (5 mL minimum) of room temperature water and swallow entire contents.

Updated June 2023–ARP Practice Committee