Sarilumab (Kevzara®)

Sarilumab (Kevzara) is a human recombinant monoclonal antibody interleukin-6 (IL-6) receptor antagonist that binds to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R) to inhibit IL-6 mediated signaling. Endogenous IL-6 is induced by inflammatory stimuli and mediates a variety of immunological responses. Inhibition of IL-6 receptors by sarilumab leads to a reduction in cytokine and acute phase reactant production.

Resources from Manufacturer

Patient Medication Guide
Full Prescribing Information
Patient Support Program
Financial Assistance

FDA-Approved Indications and Dosing in Rheumatology

Sarilumab is indicated for:

- Adult patients with moderate to severe rheumatoid arthritis (RA) who have had inadequate response to DMARDs
- Adult patients with polymyalgia rheumatica (PMR)

Subcutaneous Dosing

- RA: 200mg every 2 weeks
- PMR: 200mg every 2 weeks

Dose considerations:

- Do not initiate Sarilumab if ANC <2,000 cells/mm3, platelets <50,000 cells/mm3 or ALT/AST >1.5x ULN

	Threshold	Recommendation
ANC	500-1,000 cells/mm^3	Hold until ANC <1,000, may resume if clinically appropriate at 150mg every 2 weeks
	<500 cells/mm^3	Discontinue
Platelets	50,000-100,000 cells/mm3	Hold until platelets are >100,000 then resume at 150mg q2 weeks, can increase to 200mg if clinically appropriate
	<50,000 cells/mm3	Discontinue
ALT/ AST	<3x ULN	Dose adjust concomitant DMARDs
	3x ULN to ≤5x ULN	Hold until ALT/AST <3x ULN then resume 150mg every 2 weeks, can increase to 200mg every 2 weeks if clinically appropriate
	>5x ULN	Discontinue

Contraindications

Known hypersensitivity to sarilumab or excipients

ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

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

Warnings and Precautions

1. Serious infections–do not administer with active infection
2. Neutropenia, thrombocytopenia, elevated liver enzymes, lipid abnormalities–monitor lab parameters
3. Gastrointestinal perforation–use with caution in patients who may be at an increased risk (those with diverticulitis or concomitant use of NSAIDs or steroids)
4. Hypersensitivity reactions
5. Live vaccines–avoid use
6. Active hepatic disease or impairment

Adverse Reactions

Most common adverse reactions when used in RA (≥ 3%):

- Neutropenia
- Increased ALT
- Injection site erythema
- Upper respiratory infections
- Urinary tract infections

Most common adverse reactions when used in PMR (≥ 5%):

- Neutropenia
- Leukopenia
- Injection site pruritus

Medication Strength and Preparations

- Single-dose pre-filled syringe: 150 mg/1.14 mL, 200 mg/1.14 mL
- Single-dose prefilled auto-injector: 150 mg/1.14 mL, 200 mg/1.14 mL

Medication Administration and Storage

- Store in original carton to protect from light
- Store in refrigerator at 2°C to 8°C (36°F to 46°F)–do not freeze

Subcutaneous Administration:

- Before injecting, allow injection to warm to room temperature for 30 – 90 minutes prior to administration
- Inject subcutaneously into front of thigh, lower abdomen (avoid injecting within 2 inches of navel), or outer area of upper arm
- Do not administer into tender, bruised, red or hard skin
- Rotate injection sites (≥ 1 inch apart)
- Safe at room temperature (defined as 20°C and 25°C (68°F and 77°F)) for up to 14 days

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