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
Kevzara Co-pay Assistance Program
Kevzara Connect Patient Assistance Program

Indications and Dosing in Rheumatology

Sarilumab is indicated for:

- Adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease Modifying Anti-Rheumatic Drugs (DMARDs)
- Adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper

Dosing:

- For RA and PMR, the recommended dosage is 200 mg administered subcutaneously every 2 weeks.
- When prescribed for RA, sarilumab may be used as monotherapy or concomitantly with methotrexate or other non-biologic DMARDs
- When used for PMR, use sariluman in combination with a tapering course of corticosteroids but it can be used as monotherapy following corticosteroid discontinuation.
- Modify dosage to manage neutropenia, thrombocytopenia, and/or elevated liver transaminases.

	Threshold	Recommendation
ANC	500-1,000 cells/mm3	Hold treatment with sarilumab until ANC >1,000, then resume at 150 mg every 2 weeks and increase to 200 mg every 2 weeks as clinically appropriate.
	<500 cells/mm3	Discontinue sarilumab
Platelets	50,000-100,000 cells/mm3	Hold treatment with sarilumab until platelets <100,000, then resume at 150 mg every 2 weeks and increase to 200 mg every 2 weeks as clinically appropriate.
	<50,000 cells/mm3	Discontinue sarilumab if confirmed after repeat testing.
ALT or AST	>ULN to ≤3x ULN	Consider dosage modification of concomitant DMARDs as clinically appropriate.
	3x ULN to ≤5x ULN	Hold treatment with sarilumab until ALT/AST < 3x ULN, then resume at 150 mg every 2 weeks and increase to 200 mg every 2 weeks as clinically appropriate.
	>5x ULN	Discontinue sarilumab.

Contraindications

Known hypersensitivity to sarilumab or any of its active ingredients

Warnings and Precautions

- Serious Infections–Do not administer sarilumab during an active infection, including localized infections. If a serious infection develops, interrupt sarilumab until the infection is controlled.
- Gastrointestinal perforation–Use with caution in patients who may be at increased risk, including those with diverticulitis or concomitant use of NSAIDs or corticosteroids.
- Laboratory abnormalities–Treatment with sarilumab was associated with higher incidence of neutropenia, thrombocytopenia, elevated liver enzymes, and lipid abnormalities. Monitor 4-8 weeks after start of therapy and then every 3 months thereafter (every 6 months for lipids).
- Hypersensitivity reactions including anaphylaxis and death.
- Active hepatic disease and hepatic impairment–Use is not recommended
- Live vaccines–Avoid use with sarilumab.

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

continued

ACR/ARP Medication Guide

American College of Rheumatology
Empowering Rheumatology Professionals

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

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

Medication Administration and Monitoring

1. Prior to initiating sarilumab, test patients for tuberculosis (TB).
2. Sailumab initiation is not recommended if ANC <2,000 cells/mm3, platelets <150,000 cells/mm3 or ALT/AST >1.5x ULN. Modify dosage if neutropenia, thrombocytopenia, or liver enzyme elevations.
3. If a patient develops a serious infection, hold treatment with sarilumab until the infection is controlled.
4. Instruct patient to inject into the front of the thigh, abdomen (except for 2-inch area around the navel), or the outer area of the upper arms (if administered by a caregiver). Rotate injection sites (≥1 inch apart); do not administer into tender, bruised, red, or hard skin.

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