ACR/ARP Medication Guide

AMERICAN COLLEGE of RHEUMATOLOGY Empowering Rheumatology Professionals

ASSOCIATION of RHEUMATOLOGY PROFESSIONALS The Interprofessional Division of the American College of Rheumatology

Anakinra (Kineret)

Anakinra blocks the interleukin-1 (IL-1) receptor to help protect against autoinflammatory events. IL-1 is a proinflammatory cytokine that plays a key role in autoinflammation. Uncontrolled IL-1 activity can lead to chronic and life-threatening systemic inflammation. The impact of IL-1 is not limited to autoinflammation, but also influences the adaptive immune system, causing persistent inflammation in autoimmune diseases as well. When the IL-1 pathway is dysregulated, it creates a destructive immune response that adversely impacts a wide variety of tissues and organs.

Biosimilars

Recombinant IL1-RA / Anakinra (Kineret®Biosimilar): in development

Resources from Manufacturer

<u>Full Prescribing Information</u> <u>Patient Medication Guide</u> <u>Kineret Co-pay Card</u> <u>Kineret On Track Patient Assistance</u>

Indications and Dosing in Rheumatology

*FDA approved indications

Pediatrics

- Deficiency of interleukin 1 receptor antagonist (DIRA): 1 to 2 mg/kg/dose subcutaneously once daily; maximum 8mg/kg/dose
- Familial Mediterranean Fever (FMF), colchicine-resistant: 1 to 2 mg/kg/dose subcutaneously once daily; maximum 100mg/dose
- Juvenile Idiopathic Arthritis: systemic-onset JIA (so-JIA): 1 to 2mg/kg/dose subcutaneously once daily; maximum initial dose 100mg, may titrate at 2 week intervals to max of 200mg
- Polyarticular JIA: 1mg/kg subcutaneously once daily; maximum 100mg
- Kawasaki disease, refractory to IVIG:
- MISC associated with SARS-CoV-2: IV/SUBQ: 5 to 10mg/kg/day in 1 to 4 divided doses; while poorly documented IV may be preferred for this indication
- NOMID (Muckle-Wells)*: 1 to 2 mg/kg/day; maximum dose 8mg/kg/day

continued

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Indications and Dosing in Rheumatology continued

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Adults

- Bechet disease, mucocutaneous, refractory: 100mg subcutaneously once daily, may increase to 200mg once daily if needed
- COVID-19, hospitalized: 100mg subcutaneously once daily for 10 days
- Cytokine storm syndromes: IV: 2 mg/kg/hour as a continuous infusion for up to 72 hours, or 2 to 10 mg/kg/day in 2 to 4 divided doses; use in combination with corticosteroids;
 SUBQ: 2 to 10 mg/kg/day in 2 to 4 divided doses; use in combination with corticosteroids
- DIRA*: 1 to 2 mg/kg daily, max dose of 8mg/daily
- FMF: 100mg subcutaneously daily
- NOMID*: 1 to 2 mg/kg daily in 1 to 2 divided doses; adjust dose in 0.5 to 1 mg/kg increments as needed; usual maintenance dose: 3 to 4 mg/kg daily; maximum: 8 mg/kg daily
- Pericarditis, recurrent: 100mg subcutaneously once daily, usual duration about 6 months followed by tapering
- Rheumatoid arthritis*: 100mg subcutaneously once daily
- Still's Disease: 100mg subcutaneously once daily, used in combination with other immunosuppressants
- Gout: 100mg subcutaneously once daily until symptom improvement, generally 3 to 5 days

Contraindications

Known hypersensitivity to E. coli derived proteins, Kineret or components.

Warnings and Precautions

- Serious Infections—do not administer anakinra during an active infection, including localized infections. If a serious infection develops, interrupt anakinra until the infection is controlled
- Should not be used in combination with Tumor Necrosis Factor (TNF) blocking agents
- Live vaccines should not be given concurrently with anakinra
- Hypersensitivity reactions have been reported
- Neutrophil counts should be monitored prior to initiating anakinra and every 3 months during treatment, then quarterly for a period up to one year.

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Adverse Reactions (insert % per package insert)

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Pain, redness, swelling, or other reaction where the injection was given
- Headache
- Diarrhea, nausea, and vomiting
- Joint pain
- Signs of a common cold
- Nose or throat irritation
- Flu-like signs
- Stomach pain

Medication Strength and Preparations

- Anakinra is supplied as prefilled syringe 100mg/0.67 mL
- Should be store under refrigeration 2°C to 8°C

Medication Administration and Monitoring

- SUBQ: Rotate injection sites; inject into outer area of upper arms, abdomen (do not use within 2 inches of belly button), front of middle thighs, or upper outer buttocks; injection should be given at least 1 inch away from previous injection site; do not administer into tender, swollen, bruised, red, or hard skin or skin with scars or stretch marks. Allow solution to warm to room temperature prior to use (30 minutes). Do not shake.
- IV: Very limited data available: Administer over 1 to 3 minutes (Tremoulet 2016) or over 30 minutes (Phadke 2021). Longer infusion times (up to 3 hours) have been described in pharmacokinetic studies in adults (Granowitz 1992).

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