

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.

Resources from Manufacturer

[Patient Medication Guide](#)
[Full Prescribing Information](#)
[Patient Support Program](#)
[Financial Assistance](#)

FDA-Approved Indications and Dosing in Rheumatology

Anakinra is indicated for:

- Rheumatoid Arthritis
- Behçet Disease*
- Cytokine storm syndromes*
- COVID-19, hospitalized
- Adult and Pediatric Neonatal onset multisystem inflammatory disease (NOMID)*
- Adult and Pediatric Deficiency of Interleukin-1 Antagonist (DIRA)*
- Pericarditis, recurrent*
- Adult and Pediatric Familial Mediterranean Fever (FMF)*
- Gout*
- Still's Disease*
- pJIA*
- Multi-system inflammatory syndrome in children associated with COVID-19*
- Kawasaki refractory to IVIG in pediatrics*

*off-label indication

Subcutaneous Dosing

- Rheumatoid Arthritis: 100mg once daily
- Behçet Disease: 100mg once daily, may increase to 200mg once daily
- Cytokine storm syndromes: 2 to 10 mg/kg/day in 2-4 divided doses
- COVID-19, hospitalized: 100mg once daily for 10 days
- Adult and Pediatric Neonatal onset multisystem inflammatory disease (NOMID)*: 1 to 2 mg/kg daily in divided doses, max 8mg/day
- Adult and Pediatric Deficiency of Interleukin-1 Antagonist (DIRA): 1 to 2 mg/kg daily, max of 8mg/day
- Pericarditis, recurrent: 100mg once daily, usually 6 months followed by taper
- Adult Familial Mediterranean Fever (FMF): 100mg once daily
- Pediatric Familial Mediterranean Fever (FMF): 1 to 2 mg/kg/dose once daily
- Gout: 100mg once daily until symptoms improve, generally 3 to 5 days
- Still's Disease: 100mg once daily
- pJIA: 1mg/kg once daily, max 100mg
- Multi-system inflammatory syndrome in children associated with COVID-19: 5 to 10mg/kg/day in divided doses

FDA-Approved Indications and Dosing in Rheumatology *continued*

Intravenous Dosing

- Multi-system inflammatory syndrome in children associated with COVID-19: 5 to 10mg/kg/day in divided doses
- Cytokine storm syndromes: 2mg/kg/hour as a continuous infusion for up to 72 hours

Contraindications

Known hypersensitivity to E coli-derived proteins, Kineret, or to any component of the product.

Warnings and Precautions

1. In RA, discontinue use if serious infection develops. In NOMID or DIRA patients, the risk of a disease flare when discontinuing anakinra treatment should be weighed against the potential risk of continued treatment. Do not initiate anakinra in patients with active infections
2. Use in combination with Tumor Necrosis Factor (TNF) blocking agents is not recommended
3. Hypersensitivity reactions, including anaphylactic reactions and angioedema, have been reported. Patients with DIRA may have an increased risk of allergic reactions, particularly in the first several weeks after starting treatment
4. The impact of treatment with anakinra on active and/or chronic infections and the development of malignancies is not known
5. Live vaccines should not be given concurrently
6. Neutrophil counts should be assessed prior to initiating treatment, and while receiving, monthly for 3 months, and thereafter quarterly for a period up to 1 year

Adverse Reactions

- RA (≥5%): injection site reaction, worsening of RA, upper respiratory tract infection, headache, nausea, diarrhea, arthralgia, flu-like symptoms and abdominal pain
- NOMID (≥10%): injection site reactions, headache, vomiting, arthralgia, pyrexia and nasopharyngitis
- DIRA (≥10%): upper respiratory tract infection, rash, pyrexia, influenza like illness, gastroenteritis

Medication Strength and Preparations

- Anakinra is supplied as prefilled syringe 100mg/0.67 mL

Medication Administration and Storage

- Should be store under refrigeration 2°C to 8°C
- Subcutaneously: 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
- Intravenous: Very little data, may be administered over 1-3 minutes or up to 30 minutes. Longer infusions have been described as well. May be diluted in 1mL Normal Saline per 1mg of anakinra

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DISCLAIMER: The information contained in this biologic reference guide is offered solely for purposes of providing health care professionals with a quick and initial reference. Before prescribing or administering any drug contained in this biologic reference guide, health professionals should read the manufacturer's complete prescribing information in order to be informed of the various clinical considerations to be taken into account. The American College of Rheumatology is providing this information as a benefit and service in furtherance of its educational mission. By providing this information, ACR is not endorsing or recommending any of the listed companies or any of their drugs or other products. The information contained in the biologic reference guides reflect the conclusions of the individual companies and not those of the ACR which specifically disclaims any responsibility or liability for the use of such information and/or for the performance of any of the drugs listed in this biologic reference guide.