ACR/ARP Medication Guide

AMERICAN COLLEGE of RHEUMATOLOGY Empowering Rheumatology Professionals

ASSOCIATION of RHEUMATOLOGY PROFESSIONALS

The Interprofessional Division of the American College of Rheumatology

Secukinumab (Cosentyx®)

Secukinumab is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor, therefore inhibiting the release of proinflammatory cytokines and chemokines.

Resources from Manufacturer

Patient Medication Guide
Full Prescribing Information
Cosentyx Co-Pay Assistance Program
Novartis Patient Assistance Foundation

Indications and Dosing in Rheumatology

Secukinumab is indicated for:

- Active Psoriatic Arthritis (PsA) in patients 2 years of age and older
- Adults with active ankylosing spondylitis (AS)
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA)
- Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
- Moderate to severe plaque psoriasis in patient 6 years and older
- Adults with moderate to severe hidradenitis suppurativa (HS)

SC Dosina:

Adult patients with PsA, AS, and nr-axSpA: Administer with or without a loading dosage

- With loading dosage: 150 mg SC at weeks 0, 1, 2, 3, and 4, and every 4 weeks thereafter
- Without loading dosage: 150 mg SC every 4 weeks

Pediatric patients with PsA: Administer SC at weeks 0, 1, 2, 3, and 4, and every 4 weeks thereafter

- Patients weighing \geq 15 kg and < 50 kg, the dose is 75 mg
- Patients weighing ≥ 50 kg, the dose is 150 mg

Enthesitis-Related Arthritis (ERA): Administer SC at weeks 0, 1, 2, 3, and 4, and every 4 weeks thereafter

- Patients weighing ≥ 15 kg and < 50 kg, the dose is 75 mg
- Patients weighing ≥ 50 kg, the dose is 150

IV Dosing:

- Administer after dilution over a period of 30 minutes
- Adult patients with PsA, AS, and nr-axSpA:
 - ☐ With loading dosage: 6 mg/kg at week 0, then 1.75 mg/kg every 4 weeks thereafter
 - ☐ Without loading dosage: 1.75 mg/kg every 4 weeks
- Maximum maintenance dose of 300 mg per infusion

Contraindications Hypersensitivity to secukinumab or any excipients.

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Warnings and Precautions

- Serious Infections—Caution should be exercised when considering use in patients with chronic infection or history of recurrent infections. Do not initiate during an active infection. If a serious infection develops, discontinue secukinumab until the infection is controlled.
- Tuberculosis–Evaluate for TB prior to initiating secukinumab
- Inflammatory bowel disease—Cases were observed in clinical trials. Caution should be used when prescribing secukinumab to patients with inflammatory bowel disease
- Eczematous eruptions—Cases of severe eczematous eruptions have occurred
- Live vaccination—Avoid use in patients treated with secukinumab
- Hypersensitivity reaction—Discontinue secukinumab if anaphylaxis or other serious allergic reaction occurs

Adverse Reactions

Most common adverse reactions for subcutaneous secukinumab (>1%):

- Nasopharyngitis
- Upper respiratory tract infections
- Diarrhea

Medication Strength and Preparations

- Single-dose pre-filled syringe: 300 mg/2 mL, 150 mg/mL, 75 mg/0.5 mL
- Single-dose prefilled auto-injector: 300 mg/2 mL UnoReady pen, 150 mg/mL Sensoready pen
- For intravenous use: 125 mg/5 mL in a single-dose vial for dilution

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
- Secukinumab does not contain a preservative; discard any unused portion
- Needle cover of pre-filled syringe and auto-injector pen contains latex

Subcutaneous Administration of Pre-filled Syringes and Pens

- Before injecting, allow 150 mg/mL pen and syringes to warm to room temperature for 15 30 minutes prior to administration. Allow 30 45 minutes for 300 mg/2mL pens and syringes.
- 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)
- If necessary, secukinumab 150 mg/mL pens and syringes may be stored for up to 4 days at room temperature (≤30°C / 86°F) and may be returned to the refrigerator. Discard secukinumab if kept outside of the refrigerator and not used within 4 days.

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Intravenous Preparation and Administration

- Secukinumab vials must be diluted prior to infusion. Use aseptic technique and follow package insert directions.
- Calculate the total volume of secukinumab solution (in mL) required based on the patient's actual body weight (loading dose of 6 mg/kg = 0.24 mL/kg or maintenance dose of 1.75 mg/kg = 0.07 mL/kg).
- Before dilution, allow secukinumab solution in vial(s) to sit for approximately 20 minutes at room temperature (68°F to 77°F).
- Parenteral drug product should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if particulates or discolorations are noted.
- Use a 100 mL infusion bag of 0.9% Sodium Chloride Injection for loading dose or maintenance dose if patient body weight is > 52 kg. Use a 50 mL infusion bag for maintenance dose if patient weight is ≤ 52 kg.
- Withdraw and discard a volume from the infusion bag equivalent to the calculated volume of secukinumab solution required for the patient's dose.
- From the secukinumab vial(s), withdraw the calculated volume of secukinumab solution and add slowly to the infusion bag. To mix the solution, gently invert the bag to avoid foaming. Do not shake. Discard unused secukinumab product in vials because it does not contain preservatives.
- Administer diluted secukinumab solution for infusion as soon as possible. If not administered immediately, store the diluted solution either:
 - □ At room temperature 20°C to 25°C (68°F to 77°F) for no more than 4.5 hours from the start of the preparation (piercing the first vial) to the completion of infusion.
 - Under refrigeration at 2°C to 8°C (36°F to 46°F) for no more than 24 hours, from the start of the time of the preparation (piercing the first vial) to the completion of infusion.
- For administration, use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 0.2 micrometer). Administer the infusion at a flow rate of about 3.3 mL/minute for a 100 mL bag or 1.7 mL/min for a 50 mL bag (total administration time: 30 minutes).
- When administration is complete, flush the line with at least 50 mL of 0.9% Sodium Chloride Injection, USP to guarantee that all the secukinumab solution for infusion in the line has been administered.
- Do not infuse concomitantly in the same intravenous line with other drugs.

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