# 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 (Cosentyx<sup>®</sup>) 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

### Dosing:

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

## 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
- 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
- Lyophilized powder in a single-dose vial for reconstitution (healthcare professional use only): 150 mg

## **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 ( $\geq 1$  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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## Subcutaneous Administration of Reconstituted Vial of Lyophilized Powder

- Preparation, reconstitution, and administration should only be completed by trained healthcare provider using aseptic technique without interruption, on average taking 20 minutes and should not exceed 90 minutes.
- Remove the vial from the refrigerator and allow to stand for 15-30 minutes to reach room temperature.
- Slowly inject 1 mL of sterile water for injection into the vial of lyophilized powder.
- Tilt the vial at an angle of approximately 45 degrees and gently rotate between fingertips for approximately 1 minute. Do not shake or invert the vial.
- Allow the vial to stand for 10 minutes at room temperature to allow for dissolution. Note that foaming may occur.
- Tilt the vial at an angle of approximately 45 degrees and gently rotate between fingertips for another minute approximately.
- Allow the vial to stand for 5 minutes at room temperature. The reconstituted solution should be essentially free of visible particles, clear to opalescent, and colorless to slightly yellow. Do not use if powder is not fully dissolved, liquid contains visible particles, cloudy or discolored.
- After preparing the required number of vials (1 vial for 150 mg dose, 2 vials for 300 mg dose), administer subcutaneously.
- Reconstituted solution may be stored in the refrigerator for up to 24 hours. Do not freeze. Allow solution to reach room temperature (15 30 minutes) before administration, but not more than 1 hour.

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