

## Ustekinumab (Stelara®)

Ustekinumab is a human immunoglobulin G1k monoclonal antibody that binds to the p40 subunit of the following cytokines: interleukin-12 (IL-12) and interleukin-23 (IL-23).

### Resources from Manufacturer

[Patient Medication Guide](#)

[Full Prescribing Information](#)

[Patient Support Program](#)

[Janssen Patient Assistance Program](#)

[J&J Patient Assistance Program](#)

### Ustekinumab-auub (Wezlana) Resources from Manufacturer

[Full Prescribing Information, Patient Medication Guide, and Instructions for Use](#)

### Ustekinumab-aekn (Selarsdi) Resources from Manufacturer

[Full prescribing information, Patient Medication Guide, and Instructions for Use](#)

## FDA-Approved Indications and Dosing in Rheumatology

### Ustekinumab is indicated for:

- Adults and pediatric patients ≥ 6 years with psoriatic arthritis (PsA)
- Adults and pediatric patients ≥ 6 years with moderate-to-severe plaque psoriasis (PsO)
- Adults with moderately to severely active Crohn's disease (CD) or ulcerative colitis

### Subcutaneous dosing: Initial dose at week 0 and week 4 then every 12 weeks thereafter

- PsA: 45 mg
- Coexistent PsA and moderate to severe plaque psoriasis in patients >100 kg: 90 mg
- Pediatric JIA (weight-based dosing)

Weight	Dosing
< 60 kg	0.75 mg/kg
60 – 100 kg	45 mg
> 100 kg with co-existent moderate to severe psoriasis	90 mg

**Contraindications** Hypersensitivity to ustekinumab or any of its excipients

## Warnings and Precautions

1. Serious infections including tuberculosis and invasive fungal infections – avoid starting during active infection. If an infection develops, monitor carefully and hold therapy if serious.
2. Malignancies have been reported
3. Hypersensitivity reactions including anaphylaxis and angioedema have been reported
4. Posterior reversible encephalopathy syndrome (PRES) has been reported
5. Noninfectious pneumonia has been reported
6. Avoid live vaccines while on treatment

## Adverse Reactions ( $\geq 3\%$ )

- Nasopharyngitis
- Upper respiratory tract infection
- Headache
- Fatigue

## Medication Strength and Preparations

- Single-dose prefilled syringe: 45 mg/0.5 mL; 90 mg/mL
- Solution in single-dose vial: 45 mg/0.5 mL

## 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
- Inject subcutaneously into front of thigh, abdomen (avoid injecting within 2 inches of navel), outer upper arms, or buttocks
- Do not administer into tender, bruised, red or hard skin, or areas where psoriasis is present
- Insert the needle into pinched skin at 45-degree angle
- Pre-filled syringes are safe at room temperature (defined as up to 30°C [86°F]) for up to 30 days
- Needle cover on the Stelara prefilled syringe contains dry natural rubber (latex derivative), however Wezlana and Selarsdi do not

## Updated June 2024–ARP Practice Committee

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.