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
Financial Assistance

FDA-Approved Indications and Dosing in Rheumatology

Ustekinumab is indicated for psoriatic arthritis (PsA) in adults and pediatric patients ≥ 6 years old

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 (≥ 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 prefilled syringe contains dry natural rubber (latex derivative)

Intravenous Administration Pre-Infusion Checklist *continued*

Managing Infusion Reactions

1. Acute infusion reaction can occur during the administration of tocilizumab or within 24 hours of infusion. If the patient reports mild reactions (such as flushing, chills, etc.), slow down the infusion rate and assess the patient. Notify the supervising provider of the reaction.
2. For more severe reactions (such as hives, difficulty breathing, chest pain, high or low blood pressure, swelling of face and hands, fever, chills or anaphylaxis) or when mild reactions persist despite slowing the infusion, stop the infusion and treat the acute reaction. Tocilizumab should not be given to patients who have experienced anaphylaxis or other severe hypersensitivity and not re-challenged.

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