Abatacept (Orencia®)

Abatacept is selective T cell co-stimulation modulator that inhibits T cell activation by binding to CD80 and CD86, thereby blocking the interaction with CD28. The interaction with CD28 provides the costimulatory signal needed to fully activate T lymphocytes. It is a soluble fusion protein made up of the extracellular domain of human cytoxic T-lymphocyte-associated antigen 4 (CTLA-4) linked to the modified Fc portion of human G1 (IgG1).

Resources from Manufacturer

Patient Medication Guide
Full Prescribing Information
Patient Support Program
Financial Assistance

FDA-Approved Indications and Dosing in Rheumatology

Abatacept is indicated for:

- Adult patients with moderately to severely active rheumatoid arthritis (RA)
- Patients ≥ 2 years of age with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA)

Subcutaneous Dosing

- RA: may administer optional loading dose as a single intravenous infusion as per body weights listed in IV dosing section below. If IV loading dose administered, inject 125 mg under the skin within a day of the infusion followed by 125 mg under the skin every 7 days thereafter
- PsA: inject 125 mg under the skin every 7 days (without IV loading dose)
- pJIA (weight-based dosing for patients ≥ 2 years old): inject dose under the skin every 7 days

Weight	Dose
10 kg to < 25 kg	50 m
25 kg to < 50 kg	87.5 mg
≥ 50 kg	125 mg

continued

Intravenous Dosing

- RA and PsA: administer dose IV at 0, 2, and 4 weeks and then every 4 weeks thereafter as a 30-minute infusion

Weight	Dose
> 60 kg	500 mg
60 – 100 kg	750 mg
> 100 kg	1000 mg

- pJIA (weight-based dosing for patients ≥ 6 years old): administer dose IV at 0, 2, and 4 weeks and then every 4 weeks thereafter as a 30-minute infusion

Weight	Dose
< 75 kg	10 mg/kg
75 – 100 kg	750 mg
> 100 kg	1000 mg

Contraindications

None

Warnings and Precautions

1. Hypersensitivity and anaphylaxis have occurred
2. Avoid concomitant use with a TNF inhibitor
3. Serious infections–discontinue if serious infection develops
4. COPD patients may develop more frequent respiratory adverse events
5. Avoid live vaccines while on treatment or within 3 months of discontinuation
6. Screen for latent TB prior to starting treatment and treat patients with a positive screen before starting treatment
7. Screen for viral hepatitis prior to starting treatment

Adverse Reactions (≥10%)

- Headache
- Upper respiratory tract infection
- Nasopharyngitis
- Nausea

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Medication Strength and Preparations

- For intravenous infusion: 250 mg lyophilized powder in single-dose vial
- For subcutaneous use:
  - ❑ Single-dose prefilled syringes: 50mg/0.4mL, 87.5mg/0.7mL, and 125mg/1mL
  - ❑ Single-dose prefilled ClickJectTM autoinjector: 125mg/1mL

Intravenous Administration Pre-infusion Checklist

- Confirm the following:
  - ❑ Negative PPD or IGRA
  - ❑ Positive PPD/IGRA with negative chest radiograph or at least 4 weeks post-initiation of latent tuberculosis infection treatment
  - ❑ Negative hepatitis B serologic tests
  - ❑ Negative HCV antibody test
- Ask the patient if he/she:
  - ❑ Has a current or recent infection or illness
  - ❑ Is taking any anti-infective treatment
  - ❑ Is taking antibiotics
  - ❑ Has an upcoming surgery
  - ❑ Has had any recent live vaccines

If the answer is yes to any of these questions, notify the ordering provider before initiating the infusion therapy.

Intravenous Medication Preparation

1. Reconstitute each vial of lyophilized powder with 10 mL of Sterile Water for Injection, USP (direct the stream toward the inside wall of the vial) to achieve concentration of 25mg/1mL. Use only the provided silicone-free syringe with 18-21-gauge needle. Discard any solutions accidently reconstituted using a siliconized syringe.
2. Gently swirl vial to reduce foam formation until contents are completely dissolved. Do not shake. Avoid prolonged or vigorous agitation.
3. Once complete dissolution of powder achieved, vent the vial with a needle to dissipate any foam that may be present.
4. Repeat steps 1-3 if additional vials are needed for a dose
5. Must further dilute the reconstituted solution to 100 mL with below steps
6. From a 100 mL infusion bag/bottle of 0.9% NaCl injection, USP, withdraw volume equal to the volume of the reconstituted solution required for patient's dose
7. Slowly add reconstituted solution(s) into the infusion bag/bottle using the silicone-free disposable syringe provided with each vial
8. Gently mix. Do not shake the bag/bottle. Final concentration in bag/bottle will depend on amount of abatacept added but will not exceed 10 mg/mL.
9. Immediately discard any unused portion in the abatacept vial

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Medication Administration and Storage

- Protect vials from light by storing in original package until time of use
- Refrigerate vials at 2°C to 8°C (36°F to 46°F)
- Must complete infusion of diluted solution within 24 hours of reconstitution of vials
- Before administering, visually inspect diluted solution for particulate matter and discoloration–discard if any observed
- Using an infusion set and a sterile, non-pyrogenic, low-protein-binding filter (pore size of 0.2 µm to 1.2 µm), administer entire diluted solution over 30 minutes for RA, PsA, and pJIA
- Do not infuse concomitantly in the same IV line with other agents since it has not been studied

Subcutaneous Administration

- Protect from light by storing in original package until time of use
- Refrigerate syringes or autoinjectors at 2°C to 8°C (36°F to 46°F) – do not freeze
- Subcutaneous preparations are safe at room temperature (defined as up to 30°C (86°F)) for up to 8 hours
- Inject subcutaneously into front of thigh, abdomen (avoid injecting within 2 inches of navel), or, if caregiver administering, outer upper arm
- Do not administer into tender, bruised, red or hard skin
- Rotate injection sites
- Insert the prefilled syringe into pinched skin at 45-degree angle
- Insert the autoinjector into pinched skin at 90-degree angle

Managing Infusion Reactions

1. Acute infusion reaction can occur during the administration of abatacept or within 1 hour after the 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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