Belimumab (Benlysta®)

Belimumab (Benlysta®) is a BLyS-specific inhibitor that blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells. Belimumab does not bind B cells directly, but by binding BLyS, it inhibits the survival of B cells including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.

Resources from Manufacturer

Benlysta Patient Medication Guide

Benlysta Prescribing Information

Benlysta Co-pay Assistance Program

GSK Patient Assistance Foundation

Indications and Dosing in Rheumatology

Belimumab is indicated for:

- Patients aged 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy
- Patients aged 5 years and older with active lupus nephritis who are receiving standard therapy

Dosing:

Intravenous dosing for adults and pediatric patients with SLE or lupus nephritis:

- 10 mg/kg every 2 weeks for the first 3 doses, then every 4 weeks thereafter

Subcutaneous Dosing:

- Adults with SLE: 200 mg SC once weekly
- Adults with lupus nephritis: 400 mg (two 200-mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter

Contraindications

Previous anaphylaxis to belimumab.

Warnings and Precautions

- Serious Infections–Use with caution in patients with severe or chronic infections. Consider interrupting therapy if patients develop a new infection during treatment.
- Progressive Multifocal Leukoencephalopathy (PML)–Evaluate patients with new-onset or deteriorating neurological signs and symptoms for PML, and discontinue immunosuppressant therapy if confirmed.
- Hypersensitivity reactions, including anaphylaxis–Serious and fatal reactions have been reported.
- Depression and suicidality–Have been reported in clinical trials. Assess for depression and risk of suicide before treatment and monitor during therapy. Instruct patients to contact their provider if new or worsening depression, suicidal thoughts or other mood changes occur.
- Live vaccination–Avoid use with belimumab

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Adverse Reactions

Most common adverse reactions (>5%):

- Nausea
- Diarrhea
- Pyrexia
- Nasopharyngitis
- Bronchitis
- Insomnia
- Pain in extremity
- Depression
- Migraine
- Pharyngitis
- Injection site reactions (SC administration)

Medication Strength and Preparations

- Single-dose pre-filled syringe: 200 mg/mL
- Single-dose prefilled auto-injector: 200 mg/mL
- Single-dose vial (lyophilized powder for reconstitution and dilution for IV infusion):
  - ❑ 120 mg/5 mL
  - ❑ 400 mg/20 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
- The vial stoppers, autoinjectors, and pre-filled syringes are not made with natural rubber latex

Subcutaneous Administration

- Before injecting, allow injection to warm to room temperature for 30 minutes prior to administration
- Inject subcutaneously into front of thigh or lower abdomen (avoid injecting within 2 inches of navel)
- Do not administer into tender, bruised, red or hard skin
- Rotate injection sites (≥ 1 inch apart)
- Safe at room temperature (up to 30°C (86°F)) for up to 12 hours if protected from sunlight

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Intravenous Administration Pre-Infusion Checklist

- Ask the patient if he/she:
  - ❑ Has a current or recent infection or illness
  - ❑ Is taking antibiotics
  - ❑ Has an upcoming surgery
- If the answer is yes to any of these questions, notify the ordering provider before initiating the infusion therapy.

Intravenous Medication Preparation

1. Remove the vial of belimumab from the refrigerator and allow to stand for 10-15 minutes to reach room temperature.
2. Reconstitute the lyophilized powder with Sterile Water for Injection, USP using 1.5 mL for 120 mg vial or 4.8 mL for 400 mg vial.
3. Direct the stream of sterile water toward the side of the vial to minimize foaming. Gently swirl the vial for 60 seconds every 5 minutes until the powder is dissolved (typically completed within 10-15 minutes, but may take up to 30 minutes). Do not shake and protect the reconstituted solution from sunlight.
4. The reconstituted solution should be opalescent and colorless to pale yellow, and without particles. Small air bubbles are expected and acceptable.
5. For dilution, use 0.9% sodium chloride (normal saline, NS), 0.45% sodium chloride (1/2NS), or Lactated Ringer's. Belimumab is incompatible with dextrose intravenous solutions.
   a. For patients weighing ≤ 40 kg, use 100 mL bag resulting in belimumab concentration not exceeding 4 mg/mL
   b. For patient weighing > 40 kg, use 250 mL bag
6. From the 250 mL or 100 mL bag, withdraw and discard a volume equal to the volume of the reconstituted solution of belimumab required for the patient's dose. Then add the required volume of the belimumab reconstituted solution into the infusion bag. Gently invert the bag to mix. Any unused solution in the vials must be discarded. Inspect for particulate matter and discoloration prior to administration.
7. If reconstituted belimumab solution is not used immediately, store the vials protected from direct sunlight and refrigerated at 36-46 °F. Diluted solutions may be stored 36-46 °F or room temperature, however the total time from reconstitution, dilution, and completion of infusion should not exceed 8 hours.

Intravenous Medication Administration and Monitoring

1. Consider administering premedications as prophylaxis prior to intravenous dosing.
2. The diluted solution should be administered by intravenous infusion over 1 hour.
3. The infusion rate may be slowed or interrupted if the patient develops an infusion reaction.
4. The infusion must be discontinued immediately if the patient experiences a serious hypersensitivity reaction.
5. Do not infuse belimumab concomitantly in the same IV line with other agents. No physical biochemical or compatibility studies have been conducted.

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