Pegloticase (Krystexxa®)

Pegloticase is a recombinant, PEGylated uricase made from mammalian uricase via a genetically modified strain of E. coli. As an enzyme, it converts uric acid to allantoin, thus, reducing serum uric acid.

Resources from Manufacturer

Patient Medication Guide
Full Prescribing Information
Patient Support Program
Financial Assistance

Indications and Dosing in Rheumatology

Pegloticase is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy

Intravenous Dosing

- 8 mg IV every 2 weeks with or without methotrexate
- May be given monotherapy if methotrexate is not clinically appropriate
- If co-administered with weekly oral methotrexate and folic acid, start these agents at least 4 weeks prior to starting pegloticase infusions

Contraindications

- Glucose-6-phosphate dehydrogenase (G6PD) deficiency
- History of serious hypersensitivity to Pegloticase or any of its components

Black Box Warnings

- Anaphylaxis and Infusion Reactions: Anaphylaxis and infusion reactions have been reported to occur during and after administration of pegloticase. Anaphylaxis may occur with any infusion, including a first infusion, and generally manifest within 2 hours of the infusion. However, delayed hypersensitivity reactions have also been reported. Pegloticase should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions. Pre-medicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period of time after administration of pegloticase.
- Monitor serum uric acid levels prior to each infusion and discontinue treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.
- G6PD Deficiency Associated Hemolysis and Methemoglobinemia: Screen patients at risk for G6PD deficiency. Hemolysis and methemoglobinemia have been reported with pegloticase in patients with G6PD deficiency. Pegloticase is contraindicated in patients with G6PD deficiency.

Warnings and Precautions

- Anaphylaxis may occur with any infusion, pre-medicate and monitor patients
- Infusion reactions may occur, pre-medicate and monitor patients
- Avoid use in patients with G6PD deficiency
- Congestive Heart Failure: Congestive heart failure exacerbation may occur. Monitor patients closely following infusion.
- Gout flares: Gout flare prophylaxis is recommended for at least the first 6 months of therapy

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Adverse Reactions (≥ 5%)

If co-administered with methotrexate:

- Gout flares
- Arthralgia
- COVID-19
- Nausea
- Fatigue

If pegloticase monotherapy:

- Gout flares
- Infusion reactions
- Nausea
- Contusion or ecchymosis
- Constipation
- Chest pain
- Anaphylaxis
- Vomiting

Medication Strength and Preparations

- For intravenous infusion: 8 mg/1 mL single-dose glass vials with latex-free, coated rubber stopper

Medication Administration and Storage

- Must be diluted before using. Do not administer as IV push or bolus.
- Pegloticase admixture should be only be given as IV infusion over no less than 120 minutes via gravity-feed, syringe-type pump or infusion pump
- Allow diluted solution of pegloticase to reach room temperature before administration. Never subject pegloticase vial or diluted pegloticase in infusions bags to artificial heating.
- Before preparation for use, store in carton to protect from light and refrigerate between 2°C to 8°C (36°F to 46°F)–do not freeze
- Diluted pegloticase in infusion bags is stable for 4 hours at 2°C to 8°C (36°F to 46°F) and at room temperature (20oC to 25oC, 68oF to 77oF).
- Do not shake

Intravenous Administration Pre-infusion Checklist

- Confirm the following:
  - ❑ Negative for G6PD deficiency
  - ❑ Serum uric acid levels are > 6 mg/dL, especially when 2 consecutive levels > 6 mg/dL noted
  - ❑ Patient discontinued oral urate-lowering therapy before receiving pegloticase and it was not started while on pegloticase therapy
  - ❑ Patient premedicated with antihistamines and corticosteroids to minimize risk of anaphylaxis and infusion reactions
  - ❑ Patient on gout flare prophylaxis with either NSAIDs or colchicine beginning at least 1 week prior to initiation and continuing for at least 6 months from initiation unless medically contraindicated or not tolerated.

If unable to confirm above checklist items, notify the ordering provider before initiating the infusion therapy.

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Intravenous Medication Preparation

1. Visually inspect vials for particulate matter and discoloration—do not use if either is present.
2. Use appropriate aseptic technique. Withdraw 1 mL from pegloticase vial into a sterile syringe. Inject into a single 250 mL bag of 0.9% Sodium Chloride Injection, USP or 0.45% Sodium Chloride Injection, USP for IV infusion. Do not mix or dilute with other drugs.
3. Invert infusion bag containing dilute pegloticase solution a few times to ensure thorough mixing. Do not shake.
4. Use diluted pegloticase in infusion bags within 4 hours of dilution.

Managing Infusion Reactions

If an infusion reaction occurs during administration of pegloticase, the infusion may be slowed, or stopped and restarted at a slower rate at the discretion of the physician. Consider observing patients for 1-hour post-infusion since infusion reactions can occur after completion of infusion.

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