THE NEXT STEP IS NEW KRYSTEXXA™ (pegloticase)

Injection, 8 mg/mL, for Intravenous Infusion

NEW KRYSTEXXA™ (pegloticase)

NOW APPROVED AND AVAILABLE

KRYSTEXXA™ (pegloticase) is **now approved and available** for the treatment of chronic gout in adult patients refractory to conventional therapy.

You may order the product from the specialty distributors Besse Medical, McKesson Specialty, CuraScript or Accredo, or from the wholesalers McKesson, Cardinal Health or AmerisourceBergen.

For further information, you may also:

- Visit **www.KRYSTEXXA.com** for important product-specific information and services
- **Register for future information** as it becomes available
- View the **KRYSTEXXA Preparation and Administration video**

Consider KRYSTEXXA for your adult patients with chronic gout refractory to conventional therapy.

INDICATION

KRYSTEXXA™ (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

Important Limitations of Use:

KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

Important Safety Information

WARNING: ANAPHYLAXIS and INFUSION REACTIONS

- **Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA™ (pegloticase).**
- **Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported.**
- **KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.**
- **Patients should be premedicated with antihistamines and corticosteroids.**
- **Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA.**
- **Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.**

CONTRAINDICATIONS

- **Glucose-6-phosphate dehydrogenase (G6PD) Deficiency:** Before starting KRYSTEXXA, patients at higher risk for G6PD deficiency (e.g., those of African and Mediterranean ancestry) should be screened due to the risk of hemolysis and methemoglobinemia.

WARNINGS AND PRECAUTIONS

- **Anaphylaxis:** Anaphylaxis occurred in patients treated with KRYSTEXXA. Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. However, delayed-type hypersensitivity reactions have also been reported. KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis. Patients should be pre-medicated with antihistamines and corticosteroids. Patients should be closely monitored for an appropriate period of time for anaphylaxis after administration of KRYSTEXXA.
- **Infusion Reactions:** Infusion reactions occurred in patients treated with KRYSTEXXA. KRYSTEXXA should be administered in a healthcare setting and by healthcare providers prepared to manage infusion reactions. Patients should be pre-medicated with antihistamines and corticosteroids. Monitor patients closely for signs and symptoms of infusion reactions. In the event of an infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate. If a severe infusion reaction occurs, discontinue infusion and institute treatment as needed. The risk of an infusion reaction is higher in patients who have lost therapeutic response.
- **Gout Flares:** An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including treatment with KRYSTEXXA. If a gout flare occurs during treatment, KRYSTEXXA need not be discontinued. Gout flare prophylaxis (i.e., non-steroidal anti-inflammatory drugs [NSAIDs] or colchicine upon initiation of treatment) is recommended for at least the first 6 months of therapy unless medically contraindicated or not tolerated.
- **Congestive Heart Failure:** KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some patients in clinical trials experienced exacerbation. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion.
- **Re-treatment:** Patients receiving re-treatment may be at increased risk for anaphylaxis and infusion reactions and should be monitored carefully.

ADVERSE REACTIONS

The most commonly reported serious adverse reactions are anaphylaxis, infusion reactions and gout flares. Most common adverse reactions: gout flares (77%), infusion reactions (26%), nausea (12%), contusion or ecchymosis (11%), nasopharyngitis (7%), constipation (6%), chest pain (6%), anaphylaxis (5%), and vomiting (5%).

Please click on link to see the Full Prescribing Information, including Boxed Warning and the Medication Guide.