DO YOU HAVE A PATIENT YOU WANT TO RECOMMEND TO AN ALTERNATE SITE OF CARE? DOWNLOAD THE FOLLOWING RESOURCE TO RECOMMEND INFUSION OF KRYSTEXXA.

This template should be printed on the physician’s letterhead. The physician is responsible for completing this letter in a way that completely and accurately represents the patient’s circumstances.

Note: This content is a suggestion only.
INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE
KRISTEXXA® (pegloticase) is indicated for the treatment of chronic gout in adult 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: KRISTEXXA 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 KRISTEXXA. 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. KRISTEXXA 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 KRISTEXXA. 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.

The risk of anaphylaxis and infusion reactions is higher in patients who have lost therapeutic response. Concomitant use of KRISTEXXA and oral urate-lowering agents may blunt the rise of sUA levels. Patients should discontinue oral urate-lowering agents and not institute therapy with oral urate-lowering agents while taking KRISTEXXA.

In the event of anaphylaxis or infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate. Inform patients of the symptoms and signs of anaphylaxis, and instruct them to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

CONTRAINDICATIONS: G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA
Screen patients for G6PD deficiency prior to starting KRISTEXXA. Hemolysis and methemoglobinemia have been reported with KRISTEXXA in patients with G6PD deficiency. Do not administer KRISTEXXA to these patients.

GOUT FLARES
An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including treatment with KRISTEXXA. If a gout flare occurs during treatment, KRISTEXXA need not be discontinued. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRISTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

CONGESTIVE HEART FAILURE
KRISTEXXA has not been studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. Exercise caution when using KRISTEXXA in patients who have congestive heart failure and monitor patients closely following infusion.

ADVERSE REACTIONS
The most commonly reported adverse reactions in clinical trials with KRISTEXXA are gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

To report SUSPECTED ADVERSE REACTIONS, contact Horizon Pharma Rheumatology LLC at 1-866-479-6742 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information, including Boxed Warning.