

PATIENT NAME: _____
First Last

DATE OF ADMINISTRATION: ____/____/____



STEP 1: CONFIRM

PRIOR TO THE FIRST INFUSION

- Confirm the patient has normal G6PD* activity from lab tests and has discontinued taking urate-lowering therapies (eg, allopurinol, febuxostat)
 - **Do not administer** KRYSTEXXA® (pegloticase) to patients with G6PD deficiency

PRIOR TO EACH SUBSEQUENT INFUSION

- Confirm sUA level was tested, preferably in the last 48 hours, beginning after the first infusion
 - Notify prescribing healthcare provider (HCP) if sUA level has not been tested or if the preinfusion sUA level is >6 mg/dL, and consider discontinuing therapy, particularly after 2 preinfusion sUA levels are >6 mg/dL
- Remind the patient why they are not taking oral urate-lowering therapies and ensure they are taking gout flare prophylaxis



STEP 2: COUNSEL

- Describe to the patient how KRYSTEXXA works, including the risk of infusion reactions, using the Patient Counseling Tool
- Answer any questions the patient may have regarding treatment with information found in the KRYSTEXXA Clinical Handbook and provide a Medication Guide
- Remind the patient that they may have gout flares, and KRYSTEXXA therapy can be continued regardless of gout flares
 - A **Patient Access Manager (PAM)** is available to support the patient throughout therapy. Please refer to the Reimbursement Guide or KRYSTEXXAhcp.com for more information on how to request a **PAM**



STEP 3: PREPARE AND ADMINISTER

- Administer pretreatment medications per prescribing HCP's orders
 - IV corticosteroid _____
 - Antihistamine _____
 - Oral analgesic _____
- Visually inspect vial for particulate matter and ensure solution is clear and colorless
- Using aseptic technique, withdraw 1 mL into a sterile syringe and inject into a 250 mL bag of normal or half-normal saline. Gently mix the bag by inverting several times and discard any unused portion of the remaining product. **Do not shake**
 - No loading dose recommended or required
 - KRYSTEXXA is a single-dose vial
- The diluted solution should be used within 4 hours
- Before administration, allow the diluted solution of KRYSTEXXA to reach room temperature
 - Artificial heating should not be used
 - If not administered immediately, it is recommended that the diluted solution should be stored in the refrigerator and away from light
- Initiate infusion at a rate of 125 mL/h or slower via infusion pump or gravity feed
 - Infuse over no less than 2 hours
 - DO NOT ADMINISTER AS INTRAVENOUS PUSH OR BOLUS**
- The sticker on the KRYSTEXXA box is available for use on your patient's chart, if desired
- Use your normal protocol to monitor for infusion reactions
 - In the event of an infusion reaction, as clinically indicated, the infusion can be slowed or stopped and restarted at a slower rate. Reference the KRYSTEXXA Clinical Handbook for more information



STEP 4: OBSERVE AND REMIND

- Observe the patient for approximately 1 hour postinfusion
- Remind the patient of their next sUA test and KRYSTEXXA infusion appointments
 - KRYSTEXXA should be given every 2 weeks—it is recommended to provide a standing order to the lab to check the patient's sUA level prior to each infusion

IV=intravenous; sUA=serum uric acid.

*G6PD deficiency is an abnormally low level of glucose-6-phosphate dehydrogenase. Patients of African, Mediterranean, and Southern Asian ancestry have a higher risk of G6PD deficiency.

Please see Important Safety Information on following page and click for [Full Prescribing Information](#), including Boxed Warning.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

KRYSTEXXA® (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: 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. 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.

The risk of anaphylaxis and infusion reactions is higher in patients who have lost therapeutic response.

Concomitant use of KRYSTEXXA 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 KRYSTEXXA.

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 KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. Do not administer KRYSTEXXA to these patients.

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 with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

CONGESTIVE HEART FAILURE

KRYSTEXXA has not been studied in patients with congestive heart failure, but some patients in the clinical trials experienced exacerbation. Exercise caution when using KRYSTEXXA 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 KRYSTEXXA 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**.



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