IMPORTANT: SCREEN FOR G6PD DEFICIENCY

PRIOR TO THE FIRST INFUSION: Confirm the screening results for G6PD deficiency

**KRYSTEXXA is contraindicated in patients with G6PD deficiency**

- G6PD-deficient patients may experience life-threatening hemolytic reactions and methemoglobinemia
- It is important to test patients for G6PD deficiency prior to initiating treatment because they often appear asymptomatic and will likely not be aware of this deficiency

**WHAT IS G6PD DEFICIENCY?** G6PD deficiency is a genetic disorder that causes red blood cells to break down prematurely or in response to certain medications, including KRYSTEXXA. It is the most common enzyme deficiency disorder of red blood cells worldwide.3,4

**WHO IS AT THE GREATEST RISK?** G6PD deficiency is the most common enzyme deficiency disorder of red blood cells, affecting 400 million people worldwide. G6PD deficiency predominantly affects males, particularly those of African, Mediterranean, or Asian ancestry.4,5

**WHEN DO I SCREEN MY PATIENTS?** Unlike the serum uric acid (sUA) test, which should be performed prior to each infusion, the G6PD deficiency screening should be conducted one time, prior to the first infusion.1*

**HOW DO I SCREEN MY PATIENTS?** Perform a standard blood draw for lab analysis. Either a qualitative or quantitative screening can be ordered to determine G6PD deficiency.5

**HOW DO I INTERPRET SCREENING RESULTS?**

<table>
<thead>
<tr>
<th>Screening Classification</th>
<th>Interpretation</th>
<th>Recommendation1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Quantitative Value OR Negative Qualitative Result for Deficiency</td>
<td>Patient Does Not Have G6PD Deficiency</td>
<td>Can Proceed to Treatment With KRYSTEXXA as Indicated</td>
</tr>
<tr>
<td>Low Quantitative Value OR Positive Qualitative Result for Deficiency</td>
<td>Patient May Have G6PD Deficiency†</td>
<td>Do Not Administer KRYSTEXXA to Patients With G6PD Deficiency If you have questions regarding screening for G6PD deficiency, please call Medical Affairs at 1-866-479-6742</td>
</tr>
</tbody>
</table>

*Because the test results are typically returned within 2 to 3 days, G6PD screening is recommended at the time of service request form submission, or as early as possible.
† Acute hemolytic anemia, which may be the result of the patient’s medications, can produce inaccurate results. Additionally, if a patient has received a blood transfusion in the past 90 days, the transfusion could alter the test results. For either of these situations, postpone testing or consider retesting in 2 to 3 months.2,4

G6PD, glucose-6-phosphate dehydrogenase.

**INDICATIONS AND USAGE**

KRYSTEXXA® (pegolitacase) 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.

Please see Important Safety Information on following page and click for Full Prescribing Information, including Boxed Warning.
INDICATION AND IMPORTANT SAFETY INFORMATION

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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.

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