Risk Evaluation and Mitigation Strategy (REMS)

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

In order for Crealta Pharmaceuticals LLC (Craelta) to communicate certain risks about Krystexxa® (pegloticase), Craelta has worked with the FDA to develop materials to communicate the risks of:

- Anaphylaxis
- Infusion reactions
- Contraindication of use of Krystexxa in patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency
- Concurrent use of Krystexxa and urate-lowering therapies

The REMS program is designed to inform healthcare providers and patients about the risks with Krystexxa. To learn more about serious risks, read the important safety information provided in this link, including the Medication Guide, and discuss it with your patients.

The goal of the Krystexxa REMS is to inform healthcare providers about anaphylaxis, infusion reactions, and contraindication of use of Krystexxa in patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency.

Use the buttons below to access important REMS documents:

- Prescribing Information
- Medication Guide
- Dear Healthcare Professional Letter
- Medical Journal Information Piece

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.