KRYSTEXXA® (pegloticase) Infusion Order Protocol Template

Date:_____

STANDING INFUSION ORDER

	Protocol	Considerations
Labs prior to first treatment:	G6PD, baseline serum uric acid (sUA)	KRYSTEXXA is contraindicated in patients with G6PD deficiency
Labs prior to each treatment:	sUA	The KRYSTEXXA sUA monitoring protocol takes effect after the patient's first infusion
Pretreatment medications: IV corticosteroid:	( ) 200 mg hydrocortisone, or ( ) ___mg methylprednisolone (40-125 mg) Other:_____	Corticosteroid dosing may be adjusted as necessary. Administered immediately prior to each infusion
Antihistamine:	( ) ___mg diphenhydramine ( ) PO ( ) IVP ( ) ___mg fexofenadine PO, or ( ) ___mg loratadine PO Other:_____	Antihistamines can be administered both the night before and the morning of infusions
Analgesic:	( ) 1000 mg acetaminophen PO Other:_____	Administered the morning of infusions
Immunomodulator:	( ) Methotrexate 15 mg weekly (oral) Other:_____	If co-administering with methotrexate, start both weekly methotrexate and daily oral folic acid or folinic acid supplementation ≥4 weeks prior to initiating and throughout treatment with KRYSTEXXA
Gout flare prophylaxis:	NSAID or colchicine	Recommended to start at least 1 week before initiation of KRYSTEXXA therapy and last at least 6 months unless medically contraindicated or not tolerated
Dosage regimen:	KRYSTEXXA 8 mg IV Q2 weeks	The recommended dosage is KRYSTEXXA 8 mg given as an intravenous infusion every 2 weeks, co-administered with weekly oral methotrexate 15 mg and daily folic acid or folinic acid supplementation KRYSTEXXA alone may be used in patients for whom methotrexate is contraindicated or not clinically appropriate
Treatment time:	[eg, minimum 2-hour infusion, 1-hour observation]	KRYSTEXXA has a 2-hour minimum infusion time with a 125-cc/hr maximum rate. KRYSTEXXA has a 1-hour minimum postinfusion observation time
Preparation for use:	_____ mL ( ) normal saline (0.9% NaCl injection, USP for intravenous infusion), or ( ) half-normal saline (0.45% NaCl injection, USP for intravenous infusion)	A volume of 250 mL is recommended for infusion of KRYSTEXXA
Monitoring protocol:	Preinfusion sUA measurement within 48 hours before each infusion	Continue treatment if the preinfusion sUA level is ≤6 mg/dL. Discontinue treatment if levels increase to >6 mg/dL, particularly when 2 consecutive levels >6 mg/dL are observed

G6PD, glucose-6-phosphate dehydrogenase; IV, intravenous; IVP, IV push; NaCl, sodium chloride; NSAID, non-steroidal anti-inflammatory drugs; PO, taken orally; Q2, every two; USP, United States Pharmacopeia.

DO NOT ADMINISTER KRYSTEXXA AS AN INTRAVENOUS PUSH OR BOLUS.
USE APPROPRIATE ASEPTIC TECHNIQUE.

Please see Important Safety Information on the following page and Full Prescribing Information, including Boxed Warning, or visit KRYSTEXXAhcp.com.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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.

Limitations of Use: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS AND INFUSION REACTIONS, G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA

- **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. Delayed hypersensitivity reactions have also been reported.**
- **KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.**
- **Premedicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period after administration of KRYSTEXXA.**
- **Monitor serum uric acid levels prior to each infusion and discontinue treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.**
- **Screen patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA is contraindicated in patients with G6PD deficiency.**

CONTRAINDICATIONS:

- In patients with G6PD deficiency.
- In patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components.

WARNINGS AND PRECAUTIONS

Gout Flares: An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including KRYSTEXXA. 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 formally studied in patients with congestive heart failure, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Exercise caution in patients who have congestive heart failure and monitor patients closely following infusion.

ADVERSE REACTIONS

The most commonly reported adverse reactions (≥5%) are:

KRYSTEXXA co-administration with methotrexate trial:

KRYSTEXXA with methotrexate: gout flares, arthralgia, COVID-19, nausea, and fatigue; KRYSTEXXA alone: gout flares, arthralgia, COVID-19, nausea, fatigue, infusion reaction, pain in extremity, hypertension, and vomiting.

KRYSTEXXA pre-marketing placebo-controlled trials:

gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, and vomiting.

Please see Full Prescribing Information, including Boxed Warning, or visit KRYSTEXXAhcp.com.

AMGEN Rare Disease

KRYSTEXXA® pegloticase