# Infusion reaction prophylaxis in the clinical trials

Individual prescriber orders may vary.

| PREINFUSION MEDICATIONS[1,2] | | | |
|---|---|---|---|
| Class | Drug(s) | Dosing | Timing in relation to infusion |
| **IV corticosteroids*†** | Methylprednisolone, hydrocortisone, other | Dose determined by healthcare provider | Prior to each infusion |
| **Antihistamines*†** | Allegra® (fexofenadine), Claritin® (loratadine), Benadryl® (diphenhydramine) | | Night before infusion and/or can administer concomitantly with infusion |
| **Oral analgesic*†** | Tylenol® (acetaminophen) | | Prior to each infusion |

*To be given to the patient by a nurse on day of infusion.

†Infusion reactions may occur despite pretreatment.

# Gout flare prophylaxis

Because all patients taking KRYSTEXXA experience an initial drop in serum uric acid, it is recommended to take steps to proactively manage mobilization flares.[1‡]

| Class | Drug(s) | Dosing | Timing in relation to infusion |
|---|---|---|---|
| **Anti-gout flare agent** | Colcrys® (colchicine) | Dose determined by healthcare provider | Daily, treatment initiated 1 week prior to initiation of KRYSTEXXA and lasting at least 6 months, unless medically contraindicated or not tolerated |
| **Oral NSAIDs** | Advil® (ibuprofen), Aleve® (naproxen sodium) | | |

‡Patients may still experience gout flares despite prophylaxis.

NSAIDs, non-steroidal anti-inflammatory drugs.

**The drop in uric acid causes mobilization of uric acid crystals from stores in the body. Gout flares can be a sign that KRYSTEXXA is working to lower the uric acid in the blood.[1]**

## 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 click for Full Prescribing Information, including Boxed Warning.**

**References: 1.** KRYSTEXXA (pegloticase) [prescribing information] Horizon. **2.** Baraf HSB, et al. *J Clin Rheumatol*. 2014;20:427-432.

HORIZON



KRYSTEXXA® pegloticase