

Provider Newsflash October 2022

FDA Recall - Eugia US LLC - AuroMedics Acyclovir Sodium Injection

Purpose of this communication:

• We are writing to inform you that the FDA has published notice of a voluntary recall by Eugia US LLC (formerly AuroMedics Pharma LLC) of lot number AC22006 of AuroMedics Acyclovir Sodium Injection 500 mg per 10 mL (50 mg/mL), 10 mL single dose vials labeled with NDC 55150-154-10 and expiration date of 8/2023 that was shipped nationwide from June 8, 2022 through June 13, 2022. The recall is due to a product complaint for the presence of a dark red, brown and black particulate inside the vial. The administration of an intravenous product containing particulates has the potential to result in inflammation, allergic reaction or circulatory system complications that could be life threatening.

What do I need to do?

- Please review the following recall notice: <u>Eugia US LLC Issues Voluntary Nationwide Recall of</u>
 <u>Acyclovir Sodium Injection 500 mg per 10 mL (50 mg/mL)</u>, <u>Due to the Presence of Particulate Matter</u>
 | FDA
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.