

Provider Newsflash October, 2022

FDA Recall - Mylan Institutional, LLC Octreotide Acetate Injection

Purpose of this communication:

We are writing to inform you that the FDA has issued notice of a voluntary recall by Mylan Institutional, LLC of Octreotide Acetate Injection, 500 mcg/mL, lot AJ21002, expiry March, 2024, distributed in the US between January 11, 2022 and June 21, 2022 to the user level (hospital/pharmacy) due to a complaint of the presence of glass particulates in a syringe. Intravenous administration of a solution containing particulate matter such as glass could lead to adverse events including, but not limited to, local irritation or swelling, vasculitis/phlebitis, antigenic or allergic reactions and microvascular obstruction including pulmonary embolism.

What do I need to do?

- Please review the following recall notice: <u>FDA MedWatch One Lot of Octreotide Acetate Injection</u>,
 500 mcg/mL by Mylan Institutional (govdelivery.com)
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA 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.