

Baxter – Recall of Nexterone injection

- On November 10, 2017, [Baxter announced](#) a consumer-level recall of one lot of [Nexterone \(amiodarone\)](#) injection due to the potential presence of particulate matter identified as polyethylene in the solution. Polyethylene is a primary component of the film and ports used to manufacture these bags.
- Baxter does not anticipate a supply disruption due to this recall. The affected lot was distributed between 8/23/2017 and 10/2/2017.

| Product Description | NDC # | Lot # (expiration date) |
|--------------------------------------------------------------|--------------|----------------------------|
| Nexterone (amiodarone HCl) premixed injection, 150 mg/100 mL | 43066-150-10 | NC109925 (6/1/2019) |

- Nexterone is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy. Nexterone also can be used to treat patients with VT/VF for whom oral amiodarone is indicated, but who are unable to take oral medication. During or after treatment with Nexterone, patients may be transferred to oral amiodarone therapy.
- Intravenous administration of a solution containing sterile particulate matter may lead to adverse health consequences. The extent and severity of harm depends on the size, number, and composition of the foreign material, and the patient's underlying medical condition.
 - In the absence of in-line filtration, these particles may cause: local vein irritation, inflammatory reaction, aggravation of preexisting infections, allergic reactions, and systemic embolization.
 - To date, there have been no reports of adverse events associated with this issue.
- Anyone with an existing inventory of the recalled Nexterone injection should stop use and distribution, and contact Baxter Healthcare Center for Service at **1-888-229-0001** for return information. Contact Baxter Corporate Product Surveillance at **1-800-437-5176** for general questions regarding this recall.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled product.