Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Baxter Expands Voluntary Nationwide Recall to Include Second Lot of Nexterone Injection Due to Presence of Particulate Matter

For Immediate Release

January 16, 2018

Contact

Consumers

Baxter Corporate Product Surveillance
800-437-5176

Announcement

Following the issuance of a voluntary recall dated November 10, 2017 of one lot of NEXTERONE (amiodarone HCl) 150 mg/100 mL Premixed Injection, Baxter International Inc. announced today it is expanding the recall to include a second lot (NC109123) of NEXTERONE due to the potential presence of particulate matter. The affected lots were distributed between 7/21/2017 and 10/2/2017 in the United States to wholesalers/distributors and healthcare facilities. The particulate matter may have entered the solution during the manufacturing process.

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, phlebitis, pulmonary emboli, pulmonary granulomas, immune system dysfunction, pulmonary dysfunction, pulmonary infarction, and systemic embolization. To date, there have been no reports of adverse events associated with this issue.

NEXTERONE is a prescription antiarrhythmic agent indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation and hemodynamically unstable ventricular tachycardia in patients refractory to other therapy.

The particulate matter was identified by Baxter during a stability study, and was consistent with polyethylene, the primary constituent of the film and ports used to manufacture the bag in which NEXTERONE is packaged.

The expanded recall affects the following lots:

Product Code	Product Description	Lot Number	Expiration Date	NDC
2G3451	NEXTERONE (amiodarone HCl) Premixed Injection, 150 mg/100 mL	NC109123	5/2019	43066-150-10
2G3451	NEXTERONE (amiodarone HCl) Premixed Injection, 150 mg/100 mL	NC109925	6/2019	43066-150-10

Anyone with an existing inventory of the recalled lots should stop use and distribution and quarantine the product immediately. Inform health care professionals in your organization of this recall. If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital/retail user level. Recalled product should be returned to Baxter for credit by contacting Baxter Healthcare Center for Service at 888-229-0001, Monday through Friday, between 7 a.m. and 6 p.m. Central Time.

Customers with questions regarding this recall can contact Baxter Corporate Product Surveillance at 800-437-5176, Monday through Friday, between 8 a.m. and 5 p.m. Central Time. Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Baxter is voluntarily conducting this recall with the knowledge of the U.S. Food and Drug Administration.

Original Recall (/Safety/Recalls/ucm585155.htm)

###

- **Follow FDA (https://www.facebook.com/FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Follow @FDArecalls (https://twitter.com/fdarecalls) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**
- **Recent Recalled Product Photos on FDA's Flickr Photostream (https://www.flickr.com/photos/fdaphotos/sets/72157663245186459/) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

More in Recalls, Market Withdrawals, & Safety Alerts (/Safety/Recalls/default.htm)

Archive for Recalls, Market Withdrawals & Safety Alerts (/Safety/Recalls/ArchiveRecalls/default.htm)

Enforcement Reports (/Safety/Recalls/EnforcementReports/default.htm)

Industry Guidance (/Safety/Recalls/IndustryGuidance/default.htm)

Major Product Recalls (/Safety/Recalls/MajorProductRecalls/default.htm)