Nexterone (amiodarone HCl) 150 mg/100 mL Premixed Injection: Recall - Presence Of Particulate Matter

[Posted 11/15/2017]

AUDIENCE: Pharmacy, Cardiology, Risk Manager

ISSUE: Baxter International announced it is voluntarily recalling one lot of Nexterone (amiodarone HCl) 150 mg/100 mL Premixed Injection – distributed between 6/23/2017 and 10/2/2017 in the United States to wholesalers/distributors and healthcare facilities – due to the potential presence of particulate matter. The particulate matter may have entered the solution during the manufacturing process. The recalled lot number is NC109925.

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.

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.

BACKGROUND: 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.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: **www.fda.gov/MedWatch/report (http://www.fda.gov/MedWatch/report)**
- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/default.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

[11/15/2017 - **Press Release (/Safety/Recalls/ucm585155.htm)** - Baxter]

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