

Recall of Desmopressin Nasal Sprays by Ferring Pharmaceuticals

Date: 08/05/2020

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Ferring Pharmaceuticals has posted a market recall of DDAVP[®] Nasal Spray 10 mcg/0.1 mL, Desmopressin Acetate Nasal Spray 10 mcg/0.1 mL, and Stimate[®] Nasal Spray 1.5 mg/mL.

About this Recall:

Ferring Pharmaceuticals US is voluntarily recalling all lots on the market of DDAVP nasal spray 10 mcg/0.1mL, desmopressin acetate nasal spray 10 mcg/0.1mL, and Stimate[®] nasal spray 1.5 mg/mL. These products are being recalled due to amounts of desmopressin higher than specified. These results were obtained during routine testing.

What this means to you:

The risks associated with higher than specified amounts of desmopressin are due to abnormally low levels of sodium in the blood (e.g., hyponatremia) which could eventually lead to seizure, coma, and death. To date, Ferring has not received an increase in adverse event reports due to increased concentrations of desmopressin from users of the nasal spray. However, a single non-fatal adverse event potentially associated with this issue was reported during the timeframe that the impacted product was distributed.

DDAVP nasal spray and desmopressin nasal spray are both indicated as antidiuretic replacement therapy in the management of central cranial diabetes insipidus as well as for the management of temporary polyuria and polydipsia following head trauma or surgery in the pituitary region. Stimate nasal spray is indicated for the treatment of patients with hemophilia A with Factor VIII coagulant activity levels greater than 5% and for the treatment of patients with mild to moderate classic von Willebrand's disease (Type I) with Factor VIII levels greater than 5%.

The impacted product names, including the batch numbers and expiration dates, are available on the FDA Recall Notification, listed at the link on the following page. Patients and consumers can contact their physician or healthcare provider with any questions related to this recall.

For more information regarding this FDA Recall Notification, please refer to the FDA website:

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ferring-us-issues-voluntary-nationwide-recall-ddavpr-nasal-spray-10-mcg01ml-desmopressin-acetate>

FDA contact information for reporting adverse events/quality complaints can be reached online at

<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.