RXADVANCE
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Southborough, MA 01772

DDAVP®, desmopressin acetate and Stimate® Nasal Spray Recall Alert

Date of Notice: 08/05/2020

Brief Description of Recall Alert

Ferring Pharmaceuticals U.S. 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 listed in the table below. These drugs are being recalled due to superpotency or amounts of desmopressin higher than specified.

The risks associated with higher than specified amounts of desmopressin relate to abnormally low levels of sodium in the blood (i.e., hyponatremia), which could eventually lead to seizure, coma, and death.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
DDAVP® nasal spray 10 mcg/0.1 mL, 5 mL	55566-2500-0	N14695F	08/2020
DDAVP® nasal spray 10 mcg/0.1 mL, 5 mL	55566-2500-0	N15627C	10/2020
DDAVP® nasal spray 10 mcg/0.1 mL, 5 mL	55566-2500-0	P11319P	01/2021
DDAVP® nasal spray 10 mcg/0.1 mL, 5 mL	55566-2500-0	P11706F	04/2021
DDAVP® nasal spray 10 mcg/0.1 mL, 5 mL	55566-2500-0	R11842C	03/2022
DDAVP® nasal spray 10 mcg/0.1 mL, 5 mL	55566-2500-0	R13637E	06/2022
desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	N14695P N14695S	08/2020
desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	N15627G N15627GA	10/2020
desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	P10422A P10422AA P11319M	01/2021
desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	P10430G	03/2021
desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	P12969H P12969IR P13216G P13216P	05/2021

Drug Name & Strength	NDC	Lot	Expiration Date
desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	R11842A R11842S	03/2022
desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	R13071H	04/2022
desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	R12630A	05/2022
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	N14134C	07/2020
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	N15378G	09/2020
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	N17445N	12/2020
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	P11326AA P11326C	02/2021
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	P13209L	04/2021
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	P13212H P13755A	06/2021
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	P13756P	08/2021
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	R11845A R13271A	04/2022
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	R13648A	06/2022
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	R14101A	07/2022
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	R14667A	08/2022
Stimate® nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	R15953C	09/2022

Prescriber Information

To date, Ferring has not received an increase in adverse event reports due to increased concentrations of desmopressin from users of the nasal spray. A single non-fatal adverse event potentially associated with this issue was reported in the U.S. during the timeframe that the affected product was distributed.

Adverse reactions or quality problems experienced with the use of this drug should 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

Regular Mail or Fax: Download form 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

Member Information

RxAdvance recommends that you speak to your doctor before you stop taking the drug.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.