Ferring US – Recall of desmopressin nasal spray products

- On August 5, 2020, Ferring Pharmaceuticals announced a voluntary, consumer-level recall of several lots of DDAVP®, desmopressin acetate, and Stimate® nasal spray products due to superpotency or amounts of desmopressin higher than specified. These out of specification results were obtained during routine testing.

- The recalled lots are as follows:

Product Description	NDC#	Lot# (Expiration Date)
DDAVP nasal spray 10 mcg/0.1 mL, 5 mL	55566-2500-0	N14695F (08/2020);
		N15627C (10/2020);
		P11319P (01/2021);
		P11706F (04/2021);
		R11842C (03/2022);
		R13637E (06/2022)
Desmopressin acetate nasal spray 10 mcg/0.1 mL, 5 mL	69918-501-05	N14695P (08/2020);
		N14695S (08/2020);
		N15627G (10/2020);
		N15627GA (10/2020);
		P10422A (01/2021);
		P10422AA (01/2021);
		P10430G (03/2021);
		P11319M (01/2021);
		P12969H (05/2021);
		P12969IR (05/2021);
		P13216G (05/2021);
		P13216P (05/2021);
		R11842A (03/2022);
		R11842S (03/2022);
		R12630A (05/2022);
		R13071H (04/2022)
Stimate nasal spray 1.5 mg/mL, 2.5 mL	0053-6871-00	N14134C (07/2020);
		N15378G (09/2020);
		N17445N (12/2020);
		P11326AA (02/2021);
		P11326C (02/2021);
		P13209L (04/2021);

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		P13212H (06/2021);
		P13755A (06/2021);
		P13756P (08/2021);
		R11845A (04/2022);
		R13271A (04/2022);
		R13648A (06/2022);
		R14101A (07/2022);
		R14667A (08/2022);
		R15953C (09/2022)

- DDAVP and desmopressin nasal sprays are indicated as antidiuretic replacement therapy in the management of central cranial diabetes insipidus and for management of the 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 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.
- 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.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Contact Ferring at **1-888-337-7464** for further information regarding this recall.