

Ferring Issues Voluntary Nationwide Recall of DDAVP[®] Nasal Spray 10 mcg/0.1 mL, Desmopressin Nasal Spray 10 mcg/0.1 mL, Stimate[®] Nasal Spray 1.5 mg/mL Due to Superpotency

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Ferring Pharmaceuticals is voluntarily recalling all lots on the market 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 listed in the table on the following page to the consumer level. These products are being recalled due to superpotency or amounts of desmopressin higher than specified. These out of specification results were obtained during routine testing.

The risks associated with higher than specified amounts of desmopressin relate 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. A single non-fatal adverse event potentially associated with this issue was reported in the US during the timeframe that the affected 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%.

Ferring is notifying its distributors and wholesale customers by letter and asking them to check for impacted product and to return unused product through directions provided in the recall letter. The affected product name, including the batch numbers and expiration dates are found in the table on the following page.

Lot	Expiration Date	NDC #
DDAVP® Nasal Spray 10 mcg/0.1 mL, 5 mL		
N14695F	08-2020	55566-2500-00
N15627C	10-2020	55566-2500-00
P11319P	01-2021	55566-2500-00
P11706F	04-2021	55566-2500-00
R11842C	03-2022	55566-2500-00
R13637E	06-2022	55566-2500-00
Desmopressin Acetate Nasal Spray 10 mcg/0.1 mL, 5 mL		
N14695P	08-2020	69918-0501-05
N14695S	08-2020	69918-0501-05
N15627G	10-2020	69918-0501-05
N15627GA	10-2020	69918-0501-05
P10422A	01-2021	69918-0501-05
P10422AA	01-2021	69918-0501-05
P10430G	03-2021	69918-0501-05
P11319M	01-2021	69918-0501-05
P12969H	05-2021	69918-0501-05
P12969IR	05-2021	69918-0501-05
P13216G	05-2021	69918-0501-05
P13216P	05-2021	69918-0501-05
R11842A	03-2022	69918-0501-05
R11842S	03-2022	69918-0501-05
R12630A	05-2022	69918-0501-05
R13071H	04-2022	69918-0501-05
Stimate® Nasal Spray 1.5 mg/mL, 2.5 mL		
N14134C	07-2020	00053-6871-00
N15378G	09-2020	00053-6871-00
N17445N	12-2020	00053-6871-00
P11326AA	02-2021	00053-6871-00
P11326C	02-2021	00053-6871-00
P13209L	04-2021	00053-6871-00
P13212H	06-2021	00053-6871-00
P13755A	06-2021	00053-6871-00
P13756P	08-2021	00053-6871-00
R11845A	04-2022	00053-6871-00
R13271A	04-2022	00053-6871-00
R13648A	06-2022	00053-6871-00
R14101A	07-2022	00053-6871-00
R14667A	08-2022	00053-6871-00
R15953C	09-2022	00053-6871-00

Distributors/wholesalers with questions regarding the recall should call Stericycle at 1-888-228-5053.

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](#).
- 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.

This recall is being conducted with the knowledge of the US Food and Drug Administration.

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About Ferring Pharmaceuticals

Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. In the United States, Ferring is a leader in reproductive medicine and maternal health, and in specialty areas within gastroenterology and orthopedics. For more information, call 1-888-FERRING (1-888-337-7464); visit www.FerringUSA.com.

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

Company Contact Information

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Product Photos

Click [here](#) for product photos.