

## URGENT: VOLUNTARY PRODUCT RECALL

**Subject:            Desmopressin Acetate (Nasal Spray) 1.5 mg/mL**  
**Stimate®**  
**NDC Number: 0053-6871-00**

August 11, 2020

Dear Valued Patient,

CSL Behring is committed to ensuring that its products adhere to the highest quality standards. As such, we must notify you of a recall of Stimate® Nasal Spray. Stimate® Nasal Spray is owned and manufactured by Ferring Pharmaceuticals, Inc., and distributed and sold by CSL Behring LLC.

Ferring has issued a voluntary recall of Stimate® Nasal Spray as a precaution due to the risk of amounts of desmopressin higher than specified, also known as superpotency. This risk was identified when routine testing showed higher than expected concentrations of desmopressin in some vials of the product. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Exposure to a higher than expected amount of desmopressin can cause water retention and hyponatremia (decrease of sodium concentration in the blood). Mild symptoms can include nausea, headache and fatigue. Severe symptoms can include confusion, seizures, coma, and death as described in the Stimate® Prescribing Information. If you have medical questions about Stimate®, please contact CSL Medical Information by Phone at 1-800-504-5434 or by emailing [MedinfoNA@cslbehring.com](mailto:MedinfoNA@cslbehring.com).

You are receiving this letter because you may have received product impacted by this recall.

Patients using Stimate® Nasal Spray or their caregivers should contact their healthcare providers immediately to discuss available treatment options before returning the medication.

If you have any quantity of Stimate® Nasal Spray in your possession, please contact My Source<sup>SM</sup>, CSL Behring's Patient Resource Center at 1-800-676-4266 for instructions on how to return it as a part of this recall. To further demonstrate our commitment to the patients who use CSL Behring products, we have established a program to allow you to receive remuneration upon return of the product. If you return Stimate® Nasal Spray purchased in the U.S. on or after January 10, 2018, you may be eligible for some remuneration. Please contact My Source<sup>SM</sup>, CSL Behring's Patient Resource Center at 1-800-676-4266.

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: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.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
- Adverse events may also be reported to CSL Behring's Adverse Event Reporting line by calling 1-866-915-6958 or by emailing [adverse.events.global@cslbehring.com](mailto:adverse.events.global@cslbehring.com)

We thank you for your understanding and cooperation.



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VP Medical Affairs, CSL Behring