IMPORTANT PRESCRIBING INFORMATION

Dear Healthcare Professional:

Sanofi-aventis U.S. would like to inform you of important information regarding DDAVP® Nasal Spray (desmopressin acetate), DDAVP® Rhinal Tube (desmopressin acetate), DDAVP® Injection (desmopressin acetate), and DDAVP® Tablets (desmopressin acetate). The prescribing information for these drug products have been revised as follows:

- Removal of the Primary Nocturnal Enuresis (PNE) indication from the Nasal Spray and Rhinal Tube formulations (affects the **INDICATIONS AND USAGE, PRECAUTIONS,** and **DOSAGE AND ADMINISTRATION** sections). DDAVP Tablets are still indicated for PNE.
- Addition of a new **CONTRAINDICATION** in patients with hyponatremia or a history of hyponatremia.
- Addition of **WARNINGS** and **PRECAUTIONS** regarding hyponatremia, fluid restriction, and a recommendation to supervise administration in children.
- Addition of rare post-marketing reports of hyponatremic convulsions associated with concomitant use of oxybutinin and imipramine under **ADVERSE REACTIONS.**
- Addition of signs of overdose and a recommendation to supervise administration in children in the **OVERDOSAGE** and **PATIENT INSTRUCTION GUIDE** sections.

Please refer to the enclosed copies of the **FULL PRESCRIBING INFORMATION** for a complete discussion of the **INDICATIONS AND USAGE, CONTRAINDICATIONS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION** and **PATIENT INSTRUCTION GUIDE** for DDAVP® Nasal Spray, DDAVP® Rhinal Tube, DDAVP® Injection, and DDAVP® Tablets.

Patient safety is our highest priority at sanofi-aventis U.S. LLC, and we are committed to ensuring that healthcare professionals continue to have the information necessary to prescribe DDAVP appropriately. Please carefully review this information and contact sanofi-aventis if you should have any questions about this information or the safe and effective use of DDAVP.

We also encourage you to report any adverse events experienced by your patients. To report adverse events occurring in connection with the use of DDAVP, call 1-800-633-1610 (option #2). Alternatively, this information may be reported to FDA's MedWatch Reporting System by phone at 1-800-FDA-1088, by facsimile at 1-800-FDA-0178, or by mail using the Form 3500 available at http://www.fda.gov/medwatch/index.html.

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The current prescribing information for DDAVP Nasal Spray, DDAVP Rhinal Tube, DDAVP Injection, and DDAVP Tablets is also available on the company Web site at www.sanofi-aventis.us.

If you have further questions or require additional information, please contact our Medical Information Department at 1-800-633-1610 (option #1) from 9am to 8pm (EST) Monday–Friday.

Sincerely,

Alexandre Lebeaut
Vice President
US Medical Affairs
sanofi-aventis U.S.
Enclosures:
DDAVP® Nasal Spray (desmopressin acetate) full prescribing information
DDAVP® Rhinal Tube (desmopressin acetate) full prescribing information
DDAVP® Injection (desmopressin acetate) full prescribing information
DDAVP® Tablets (desmopressin acetate) full prescribing information