

FDA Issues Alert On Bed Wetting Drug

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Article Date: 07 Dec 2007 - 3:00 PST

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The US Food and Drug Administration (FDA) has asked the manufacturers to update drug labels and prescription information on desmopressin, available in tablet and nasal spray form and used to treat bed wetting, to include new information about severe hyponatremia, a condition caused by insufficient sodium in the blood which leads to seizures and sometimes death.

The FDA announcement explained that certain patients taking desmopressin (marketed as DDAVP Nasal Spray, DDAVP Rhinal Tube, DDAVP, DDVP, Minirin, and Stimate Nasal Spray), were at risk of "developing severe hyponatremia that can result in seizures and death".

Desmopressin reduces water elimination via urine, thus preventing excessive thirst, urination and dehydration brought about by a range of conditions such as types of diabetes, physical injury, surgery and other medical conditions.

Children who were being treated with intranasal forms of desmopressin for bed wetting or primary nocturnal enuresis (PNE) were "particularly susceptible to severe hyponatremia and seizures" said the FDA.

The warnings and restrictions apply differently to the nasal spray and other formulations of desmopressin.

Nasal spray formulations that contain desmopressin are no longer approved for the treatment of bed wetting (PNE), said the FDA, and they should not be used in patients with hyponatremia or who have a history of it. Doctors should consider other options for treating this condition, said the alert announcement issued by the FDA's Center for Drug Evaluation and Research (CDER).

Tablet, rhinal tube, and injection forms of desmopressin will also carry new information about the risk for hyponatremia, said the FDA.

Patients on the tablet form of desmopressin for bedwetting (PNE) who develop illnesses with episodes of electrolyte or fluid imbalance, characterized by fever, recurrent vomiting or diarrhea, should have their treatment interrupted. This also applies to patients who undertake vigorous exercise or have other conditions linked with increased water consumption.

For one hour before, and for 8 hours after taking desmopressin tablets, patients' fluid intake should be restricted, said the FDA.

Regardless of whether it is a tablet, nasal spray, or any other form, all desmopressin formulations should be used cautiously in patients with habitual or psychogenic polydipsia (abnormal ingestion of large amounts of fluid).

Similar caution is recommended when treating patients who are taking drugs that may cause them to drink more fluids. For example patients on tricyclic antidepressants and selective serotonin re-uptake inhibitors (SSRIs).

All patients taking desmopressin and ingesting excessive fluids are at higher risk of developing hyponatremia, said the FDA.

The FDA has received 61 reports of patients experiencing hyponatremic-related seizures linked to use of desmopressin, including two who died. The agency said it was not clear whether the deaths were directly linked to desmopressin.

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