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300
DDAVP® Nasal Spray
desmopressin acetate 5ml
Dry Nights For Good Mornings

Brief Summary

CONTRAINDICATION: Known hypersensitivity to DDAVP Nasal Spray.

1. For intranasal use only.
2. If very young or elderly patients in particular, fluid intake should be adjusted in order to decrease the potential occurrence of water retention and hyponatraemia. Particular attention should be paid to the possibility of the rare occurrence of an extreme decrease in plasma osmolality and resulting seizures.

PRECAUTIONS

General: DDAVP Nasal Spray at high dosage has occasionally produced a slight elevation of blood pressure, which disappeared with a reduction in dosage. The drug should be used with caution in patients with coronary artery disease or hypertension. It may also cause fluid retention leading to hyponatraemia. DDAVP Nasal Spray should be used with caution in patients with conditions associated with fluid and electrolyte imbalance, such as polyuria, because these patients are prone to hyponatraemia.

Central Nervous System: With DDAVP Nasal Spray, it is possible that fluid retention changes in the nasal mucosa such as swelling, exudate, or other disease may cause irritant, unresponsive absorption in which case DDAVP Nasal Spray should not be used. For such situations, DDAVP injection should be considered.

Primary Nocturnal Enuresis: If changes in the nasal mucosa have occurred, unresponsive absorption may result. DDAVP Nasal Spray should be discontinued until the nasal problem resolves.

Information for Patients: Patients should be informed that the bottle accuracy drivers (00 mg of 10 mg each) Any solution remaining after 50 doses should be discarded since the amount delivered subsequently may be substantially less than 10 mg of drug. No attempt should be made to transfer remaining solution to another bottle. Patients should be instructed to read accompanying directions on use of the spray pump carefully before use.

Laboratory Tests: Laboratory tests for following the patient with central diabetes insipidus or post-surgical or head trauma-related polyuria and polydipsia include urine volume and osmolality. In some cases plasma osmolality may be required. For the healthy patient with no renal disease, serum electrolytes should be checked at least once a week and beyond 2 days.

Drug Interactions: Although the presor activity of DDAVP Nasal Spray is very low compared to the antidiuretic activity, use of large doses of DDAVP Nasal Spray with other pressor agents should only be done with careful patient monitoring.

Concomitantly: Use with caution because the patient may be prone to hyponatraemia. No further information is available.

Pregnancy: Category B, Reproduction studies performed in rats and rabbits with doses up to 12.5 times the human intranasal dose (i.e., 125 times the total adult human dose) have yielded no evidence of harm to the fetus due to desmopressin acetate. However, no controlled studies in pregnant women have been carried out. Published reports stress that, as opposed to preparations containing the natural hormone, desmopressin acetate nasal spray (desmopressin in an antidiuretic dose) has no uterine activity, but the pregnant patient may have to lose weight possible teratogenic advantage over possible dangers in each individual case.

Nursing Mothers: There have been no controlled studies in nursing mothers. A single study in a post-partum woman demonstrated a marked change in plasma osmolality, but little if any change in excretion of urinary osmolality. DDAVP nasal spray in children should be used only in individual cases, where this is likely to be of benefit, and under medical supervision. Use in infants and children will require careful fluid intake restriction to prevent possible hyponatraemia and water retention. The dose must be individually adjusted to the patient, particularly in the very young to the danger of an extreme decrease in plasma osmolality with resulting convulsions. Dose should start at 0.5 mg or less. Since the spray cannot deliver less than 0.1 mg, (10 mg) smaller doses should be administered using the monolab tube delivery system.

ADVERSE REACTIONS: Adverse reactions have occurred with desmopressin acetate. These reactions have been reported in children with diabetes insipidus. Use in infants and children will require careful fluid intake restriction to prevent possible hyponatraemia and water retention. The dose must be individually adjusted to the patient, particularly in the very young to the danger of an extreme decrease in plasma osmolality with resulting convulsions. These reactions have been reported in children with diabetes insipidus. Use in infants and children will require careful fluid intake restriction to prevent possible hyponatraemia and water retention. The dose must be individually adjusted to the patient, particularly in the very young to the danger of an extreme decrease in plasma osmolality with resulting convulsions. Dose should start at 0.5 mg or less. Since the spray cannot deliver less than 0.1 mg, (10 mg) smaller doses should be administered using the monolab tube delivery system.

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