**Desmopressin Acetate Nasal Spray**

**10 mcg per 0.1 mL**

*For Intranasal Use Only*

**Instructions for Use**

**Desmopressin Acetate Nasal Spray, 10 mcg per 0.1 mL**

Read these instructions before using Desmopressin Acetate nasal spray, and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

**Children should be helped by an adult when using Desmopressin Acetate nasal spray, to make sure the right amount of medicine is used.**

**The parts of Desmopressin Acetate nasal spray (See Figure A):**

- Press down on the shoulders at the top of your Desmopressin Acetate nasal spray pump 4 times. Hold the tip away from your face and eyes (See Figure B).

**Figure A**

![Desmopressin Acetate nasal spray pump](image)

**Figure B**

![Press down on the shoulders at the top of your Desmopressin Acetate nasal spray pump 4 times. Hold the tip away from your face and eyes.](image)

**Figure C**

**Figure D**

![After you remove your Desmopressin Acetate nasal spray pump] (image)

**Figure E**

**Figure F**

![Instructions for Use](image)
Amring_Desmopressin Acetate Nasal Spray_PI_R7.indd 2

Figure G

Keep this chart with your Desmopressin Acetate nasal spray or put it someplace where you can easily get it.

Check off number 1 on the chart with your first dose of Desmopressin Acetate nasal spray. Check off the numbers after each use of your Desmopressin Acetate nasal spray. If your healthcare provider prescribed a 2-spray dose, then 2 numbers should be checked off.

Your Desmopressin Acetate nasal spray holds 50 sprays with the right amount of medicine in each spray.

If any medicine is left in your Desmopressin Acetate nasal spray after 50 sprays, do not use it. You may not get the right amount of medicine.

Throw away your Desmopressin Acetate nasal spray after 50 sprays.

Do not count the priming sprays. Your Desmopressin Acetate nasal spray has been filled with extra medicine for your priming sprays.

Do not try to remove any medicine from your Desmopressin Acetate nasal spray pump and place it in another bottle.

How should I store Desmopressin Acetate nasal spray?

Store Desmopressin Acetate nasal spray at room temperature between 68°F to 77°F (20°C to 25°C).

Store Desmopressin Acetate nasal spray standing upright.

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

Manufactured for: Amring Pharmaceuticals Inc. Berwyn, PA 19312 Origin Germany X00000000

Dosage and Administration

Central Ocular Diabetes Insipidus: Desmopressin Acetate Nasal Spray dosage may be determined by the physician on the basis of two parameters: adequate duration of response and response rate. The dosages utilized in adults and children are given in Table 1. Studies have demonstrated no effect of additional doses on body weight, fluid intake, and fluid output. Individuals with normal renal function may need less than 10 mcg/day. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when desmopressin acetate is administered to nursing women.

Pediatric Use: Desmopressin Acetate Nasal Spray has been used in children with diabetes insipidus. Due to infants and children will require careful fluid intake restrictions to prevent possible hyponatremia and water intoxication (see WARNINGS, PRECAUTIONS). The dose must be individually adjusted to the patient with attention in the very young to the danger of an extreme decrease in plasma osmotically resulting convulsions. Dosage should start at 0.1 mcg of Desmopressin Acetate Nasal Spray. If your healthcare provider prescribed a 2-spray dose, then 2 numbers should be checked off.

Use of Desmopressin Acetate Nasal Spray in geriatric patients will require careful fluid intake restrictions to prevent possible hyponatremia and water intoxication (see WARNINGS, PRECAUTIONS). There are reports of an occasional change in response with time, usually greater than 6 months. Some patients may show a decreased responsiveness, whereas others show an increase. This drug is known to be substantially excreted by the kidney, and the risk of basic reactions in this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be necessary to reduce the dosage of Desmopressin Acetate in patients with reduced renal function in renal failure patients on maintenance hemodialysis and/or peritoneal dialysis. These patients have also been reported to have developed water intoxication, mental status changes, delirium, and reversible cortical blindness, after the intranasal route of administration (see WARNINGS, PRECAUTIONS).

ADVERSE REACTIONS

Infringently high doses of intranasal Desmopressin Acetate have produced transient headache and nausea. Nasal congestion, rhinorrhea and flushing have also been reported occasionally with intranasal administration. These symptoms disappeared on discontinuation. Localized reactions, such as burning, flush and upper respiratory infections have also been reported. This following table lists the percent of patients having adverse reactions listed below, the percent indicating adverse drug reactions for intranasal administration.

See WARNINGS for the possibility of water intoxication and hyponatremia.

OVERDOSAGE

Signs of overdose may include confusion, benzodiazepine, central nervous system effects, problems with passing urine and rapid weight gain due to fluid retention (see WARNINGS). In case of overdose, the dose should be reduced, frequency of administration decreased, or the drug withdrawn according to the severity of the condition. There is no specific antidote for desmopressin acetate in Desmopressin Acetate Nasal Spray. In dogs (see NOVEL), an intravenous dose of 2 mg/kg has been demonstrated to be effective in restoring intravascular volume.

DOSAGE AND ADMINISTRATION

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