Desmopressin Acetate
Nasal Spray Solution, 10 mcg/0.1 mL

DESCRIPTION

Desmopressin Acetate Nasal Spray Solution, 10 mcg/0.1 mL is a synthetic analogue of the natural pituitary hormone 8-arginine vasopressin (ADH), an antidiuretic hormone. Desmopressin Acetate Nasal Spray Solution is a potent antidiuretic which, when administered, may lead to water intake and/or hyponatremia. Unless properly diagnosed and treated, hyponatremia can be fatal. Therefore, fluid restriction is recommended for all patients treated with Desmopressin Acetate Nasal Spray Solution.

CONTRAINDICATIONS

The use of Desmopressin Acetate Nasal Spray Solution is contraindicated in patients with diabetes insipidus of neurogenic origin and patients with diabetes insipidus of nephrogenic origin. Therefore, Desmopressin Acetate Nasal Spray Solution should not be used in these patients.

ADVERSE REACTIONS

The most common adverse reactions associated with the use of Desmopressin Acetate Nasal Spray Solution are headache, nausea, vomiting, weight gain, and restlessness. In rare cases, anaphylaxis has been reported with intravenous and intranasal administration. The following are the most common adverse reactions:

1. For intranasal use only

2. Oral administration may be ineffective due to the development of binding antibodies but may be due to a local inactivation of the spray pump.

3. Very rare cases of hyponatremia have been reported from world-wide postmarketing experience in patients treated with Desmopressin Acetate Nasal Spray Solution (desmopressin acetate). Desmopressin Acetate Nasal Spray Solution should be used with caution in patients with conditions associated with fluid and electrolyte imbalance, such as cystic fibrosis, heart failure and renal disorders because of possible exacerbation of these conditions.

4. When Desmopressin Acetate Nasal Spray Solution is administered, in particular in pediatric and geriatric patients, fluid intakes should be adjusted downward in order to decrease the potential for occurrence of water intoxication and/or hyponatremia. In patients receiving Desmopressin Acetate Nasal Spray Solution, the physician should be informed of any evidence of edema, headache, nausea/vomiting, decreased serum sodium, weight gain, restlessness, fatigue, lethargy, depression, disorientation, reflex loss, loss of appetite, irritability, muscle weakness, visual changes or abnormal lateral positions (such as hallucinations, decreased consciousness and confusion. Rare symptoms may include one or a combination of the following: dizziness, nausea and/or respiratory arrest. Particular attention should be paid to the possibility of the development of hyponatremia in the older population inasmuch as it may result in seizures which could lead to coma.

5. Desmopressin Acetate Nasal Spray Solution should be used with caution in patients with conditions associated with fluid and electrolyte imbalance, such as cystic fibrosis, heart failure and renal disorders because of possible exacerbation of these conditions.

PRECAUTIONS

Desmopressin Acetate Nasal Spray Solution is used intranasally, changes in the nasal mucosa such as scarring, edema, or other disease may cause erratic, unreliable absorption in which case intranasal desmopressin acetate should not be used. For such situations, desmopressin acetate injection should be considered.

Drug Interactions:

The following drug interactions are possible. These interactions may be avoided by concomitant use of drugs with the potential to cause fluid and electrolyte imbalance, such as cystic fibrosis, heart failure and renal disorders because of possible exacerbation of these conditions.

Drug Interactions:

Drugs that are eliminated by renal excretion can cause accumulation when Desmopressin Acetate Nasal Spray Solution is co-administered. These include NSAIDs, lamotrigine and carbamazepine. Use of such drugs requires close monitoring of renal function in order to decrease the risk of hypotension and/or hyponatremia.

Storage:

Store in a refrigerator at 2°-8°C (36°-46°F). When traveling, product will remain stable in a refrigerator for up to 3 weeks when stored at room temperature, 22°C (72°F).

Figure A

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**PATIENT INSTRUCTIONS**

**DELIVERING DESMOPRESSIN ACETATE MORE EFFICIENTLY**

Your doctor has prescribed Desmopressin Acetate Nasal Spray Solution as antidiuretic hormone replacement therapy. Follow the dosage and administration instructions carefully. DELIVERING DESMOPRESSIN ACETATE MORE EFFICIENTLY is an important step in ensuring that your treatment is successful and safe. Failure to prepare the spray pump in advance of use can lead to a delay in administration, thus affecting the therapeutic outcome.

1. Remove protective cap.

2. Before first use, prime the spray by removing the seal over the bottle as shown in Figure A and press down with a quick and firm motion a total of five (5) times. This initial priming is very important to ensure that you receive the correct amount of the solution when you begin to administer your treatment.

3. Once the priming process is complete, hold the bottle upright while administering the solution; it may be necessary to lean your head forward to clear nasal passages before administering.

4. Hold the bottle firmly in your hand and squeeze down firmly on the pump. You may feel the air bubble float to the top of the bottle. Tilting the bottle, excessive solution is left, may cause the pump to not dispense correctly.

5. In order to ensure dosing accuracy, it is very important to ensure that children are administered in under adult supervision in order to control the dose intake.

6. Ensure that in children administration is under adult supervision in order to control the dose intake.

7. Ensure that in children administration is under adult supervision in order to control the dose intake.

8. Ensure that in children administration is under adult supervision in order to control the dose intake.

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**Figure A**
The following table lists the percentage of patients having adverse experiences:

<table>
<thead>
<tr>
<th>ADVERSE EFFECT</th>
<th>PLACEBO</th>
<th>Desmopressin Acetate 20 mcg</th>
<th>Desmopressin Acetate 40 mcg</th>
</tr>
</thead>
<tbody>
<tr>
<td>NERVOUS SYSTEM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthenia</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Insomnia</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Headache</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hiccups</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Respiratory</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>DIGESTIVE SYSTEM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anorexia</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Nausea</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Nephritis</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>RESPIRATORY SYSTEM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epistaxis</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>SKIN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Eczema</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Lachrymation Disorder</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

Post Marketing: There have been rare reports of hypothalamic-pituitary dehiscences associated with concomitant use of the following medications: oxycodone and propofol. See WARNINGS for the possibility of water intoxication and hyponatremia.

Bausch + Lomb, a division of Valeant Pharmaceuticals North America LLC

1. 5 mL - NDC 24284-340-56
2. 10 mL - NDC 24284-341-17
3. 20 mL - NDC 24284-342-78

To report SUSPECTED ADVERSE REACTIONS, contact Valeant Pharmaceuticals North America LLC, 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Dosage and Administration

Desmopressin Acetate Nasal Spray Solution is supplied as a sterile, aqueous solution of desmopressin acetate in an aerosol propellant system, following an intranasal dose of 10 mcg. It is not known whether this drug is excreted in human milk. Therefore, caution should be used in nursing women.

Pediatric Use

The safety and efficacy of desmopressin acetate in children have not been established in children less than 6 months of age. Therefore, its use in this population is not recommended.

Geriatric Use:

The use of desmopressin acetate nasal spray in patients 65 years of age and older has been reported. There is no evidence of either increased or decreased efficacy in this age group. Therefore, the use of desmopressin acetate nasal spray is not recommended in patients less than 6 months of age. Its use in patients 65 years of age and older should be limited to those in whom the benefit outweighs the potential risk.

WARNINGS

1. Water intoxication may occur with dosages in excess of 10 mcg. The dose should be reduced or discontinued if signs and symptoms of water intoxication occur.

OVERDOSAGE

1. Water intoxication may occur with dosages in excess of 10 mcg. The dose should be reduced or discontinued if signs and symptoms of water intoxication occur.

2. The spray pump must be primed prior to the first use. To prime the pump, press down on the cap. About 1/4 to 1/3 of patients can be controlled by a single daily dose of desmopressin acetate administered intranasally. Fluid restriction should be observed. (See WARNINGS, PRECAUTIONS, Pediatric Use and Geriatric Use.)

3. Desmopressin Acetate Nasal Spray Solution after 50 sprays since the amount of drug delivered thereafter per spray may be substantially less than 10 mcg of drug. The spray pump must be primed prior to the first use. To prime the pump, press down on the cap.