**Desmopressin Acetate Tablets**

**Rx only**

**DESCRIPTION**

Desmopressin Acetate Tablets are synthetic analogs of the natural pituitary hormone, 8-arginine vasopressin (ADH), an antidiuretic hormone used under controlled conditions, to treat central diabetes insipidus (CDI) chemically defined as follows: MK. Wt: 1183.34

Empirical formula: C64H124N14O12

\[\text{C}_6\text{H}_4\text{C}_1\text{C}_2\text{N}_2\text{O}_{12}\]

**CLINICAL PHARMACOLOGY**

Desmopressin Acetate Tablets contain active substance, desmopressin acetate, a synthetic analog of the natural hormone arginine vasopressin.

**Central Diabetes Insipidus**: Dose response studies in patients with diabetes insipidus have demonstrated that oral doses of 0.2 mg and 0.4 mg produced a marked suppression of urine output. In most patients, the diuresis was abolished and the antidiuretic effect lasted up to 8 hours. With doses of 0.4 mg, antidiuretic effects were observed for up to 12 hours in many patients. Patients treated for more than 2 months showed no increasing trend in urine output and no side effects dependent on dose were observed.

The plasma half-life of Desmopressin Acetate Tablets followed a monoexponential time course with \( t_{1/2} \) values of 1.5 to 2.5 hours and the drug was eliminated in the urine.

The bioavailability of Desmopressin Acetate Tablets is about 5% compared to intranasal desmopressin acetate, and about 0.16% compared to the intranasal spray. Desmopressin acetate tablets are a potent antidiuretic which, when administered, may lead to water intoxication and/or hyponatremia.

**Administration and Dosage**

Desmopressin Acetate Tablets tablets are indicated for the management of primary nocturnal enuresis.

**CLINICAL PHARMACOLOGY**

In another study of adult diabetes insipidus patients previously controlled on desmopressin acetate intranasal spray, after one week of treatment with placebo and 0.1 mg and 0.3 mg oral doses, no significant difference was observed in the 46 patients who were treated with Desmopressin Acetate Tablets for periods of 12 to 44 months were reported.

In one study, the pharmacokinetic characteristics of Desmopressin Acetate Tablets and intranasal formulation were compared during an 8-hour period. The rise in urine osmolality was less rapid and the peak rise of 270 mOsm/kg was seen at 4 hours with tablets every 8 hours. 0.1, 0.2, 0.4 mg orally and 0.1 mg intranasally by nasal route. The results are shown in the following table:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Total Urine Volume (mL/min)</th>
<th>Maximum Osmolality (mOs/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>1.0 (0.3)</td>
<td>3 (0.4)</td>
</tr>
<tr>
<td>Desmopressin Acetate Tablets</td>
<td>1.0 (0.2)</td>
<td>7 (0.5)</td>
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</table>

**CONTRAINDICATIONS**

Desmopressin Acetate Tablets are contraindicated in individuals with known hypersensitivity to desmopressin acetate or to any of the components of Desmopressin Acetate Tablets.

**WARNINGS**

1. In some cases of hyponatremia, have been reported from worldwide postmarketing experience in patients treated with Desmopressin Acetate Tablets. Desmopressin Acetate Tablets are a potent antidiuretic which, when administered, may lead to water intoxication and/or hyponatremia. Unless properly diagnosed and treated hyponatremia can be fatal. Therefore, fluid restriction is recommended and should be discussed with the patient and/or guardian. Critical medical supervision is required.
2. When Desmopressin Acetate Tablets are administered, in particular in pediatric and geriatric patients, fluid intake should be adjusted according to the diurnal pattern of response. (See Dosage and Administration.)

5. The clinical studies and animal studies have provided no indication of embryo/fetal toxicity. As with other medications, there is a possibility of fetal injury when Desmopressin Acetate Tablets are administered to a pregnant woman. (See Animal Studies and Reproductive Toxicity.)

6. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients who have impaired renal function. (See Clinical Pharmacology and CONTRAINDICATIONS.)

7. The only controlled clinical trials conducted with Desmopressin Acetate Tablets that was probably, possibly, or remotely related to study drug was headache (4% Desmopressin Acetate Tablets, 8% Placebo).

8. The following adverse events have been reported; however their relationship to desmopressin acetate has not been firmly established: dry mouth, flushing, diarrhea, and altered menses. (See WARNINGS for the possibility of water intake and hyponatremia.)

9. There have been no controlled studies in nursing mothers. An.NAME has been reported rarely with intravenous and intranasal administration of desmopressin acetate but not with Desmopressin Acetate Tablets.