CONTRAINDICATIONS

DESMOPRESSIN ACETATE Injection 4 mcg/mL Rx only

DESCRIPTION

DESMOPRESSIN ACETATE Injection (desmopressin acetate 4 mcg/mL) is a synthetic analogue of the natural posterior pituitary hormone arginine vasopressin (ADH), an antidiuretic hormone affecting renal water conservation. It is chemically defined as follows:

C2H4O2

O

H2N-C(=NH)-C(=O)-C6H4-OH

H3C

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 with severely impaired renal function. Careful medical supervision is required. In patients with severe renal impairment, the usual dosage range in adults is 0.5 mL (2.0 mcg) to 1 mL (4.0 mcg) daily, administered intravenously or subcutaneously, usually in two divided doses as large as 0.3 mcg/kg of DESMOPRESSIN ACETATE with other pressor agents should be done only with careful patient monitoring.

Laboratory tests for monitoring the patient include urine volume and osmolality. In some cases, plasma osmolality may be decreased.

When administered by injection, DESMOPRESSIN ACETATE has an antidiuretic effect about ten times that of an equivalent dose of vasopressin (ADH), an antidiuretic hormone affecting renal water conservation. It is chemically defined as follows:

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However, the spontaneous activity of von Willebrand's disease activity was also increased to a smaller degree, but still are dose-dependent.

Hemophilia A: DESMOPRESSIN ACETATE Injection

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Eight related antigen and ristocetin cofactor activity were also increased to a smaller degree, but still are dose-dependent.

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WARNINGS
There have been rare reports of thrombotic events following DESMOPRESSIN ACETATE Injection with caution in patients with coronary artery insufficiency and/or hypertensive cardiovascular disease.

General:
1. The biphasic half-lives of DESMOPRESSIN ACETATE were 7.8 and 75.5 minutes for the fast and slow phases, respectively, compared with placebo. If there are 2 or 3 days between administrations.

2. The change in structure of arginine vasopressin to DESMOPRESSIN ACETATE has resulted in a decreased vasopressor action and decreased effects on visceral smooth muscle relative to the enhanced antidiuretic activity, so that clinically effective antidiuretic doses are usually well below levels that would be expected to produce vasopressor effects.

3. The effect of repeated DESMOPRESSIN ACETATE administration when doses were given every 12 to 24 hours has generally shown a tendency toward tachyphylaxis (lessening of response) with repeated dose administration. Laboratory response as well as the clinical condition of the patient. The tendency toward tachyphylaxis (lessening of response) with repeated dose administration given more frequently than every 4 hours should be considered in treating each patient.

4. There is no specific antigenic activity for desmopressin acetate or DESMOPRESSIN ACETATE Injection 4 mcg/mL.

5. Infrequently, DESMOPRESSIN ACETATE has produced transient headache, nausea, mild abdominal cramps and vulval pain. These symptoms disappeared with reduction in dosage. Occasionally, injection of DESMOPRESSIN ACETATE has produced local exanthema, urticaria or burning sensation.

6. Plasminogen activator activity increases rapidly after DESMOPRESSIN ACETATE infusion, but there has been no clinically significant increase in fibrinolytic activity. The plasminogen activator is dose-related, with maximal plasma levels of 300 to 400 percent of initial concentrations obtained after infusion of 0.4 mcg/kg body weight in adult patients with hemophilia and von Willebrand's disease Type I.

7. The effect of repeated DESMOPRESSIN ACETATE administration when doses were given every 12 to 24 hours has generally shown a tendency toward tachyphylaxis (lessening of response) with repeated dose administration given more frequently than every 4 hours should be considered in treating each patient.

8. There is no specific antigenic activity for desmopressin acetate or DESMOPRESSIN ACETATE Injection 4 mcg/mL.

9. An oral LD₅₀ has not been established. An intravenous dose of 2 mg/kg in mice demonstrated no effect.

DOSE AND ADMINISTRATION
Pediatric Use: Children and in pediatric patients will require careful fluid intake restriction to prevent possible hyponatremia and water intoxication. Fluid restriction should be discussed with the patient and/or guardian. (See WARNINGS.) DESMOPRESSIN ACETATE Injection 4 mcg/mL is available as a sterile solution in cartons of ten 1 mL single-dose ampules (NDC 69918-899-10).

Hemophilia A: DESMOPRESSIN ACETATE Injection 4 mcg/mL is administered as an intravenous infusion at a dose of 0.3 mcg DESMOPRESSIN ACETATE/kg body weight diluted in sterile physiological saline and infused slowly over 15 to 30 minutes. The usual dosage range in adults is 0.5 mL (2.0 mcg) to 1 mL (4.0 mcg) daily, administered intramuscularly or subcutaneously, as needed. In older males, the usual dosage range is 10 to 50 mcg/day. In older females, the usual dosage range is 5 to 25 mcg/day.

Contraceptives: No alterations in the contraceptive effectiveness of DESMOPRESSIN ACETATE have been observed.

Pediatric Use:
Other reported clinical experience has not identified differences in absorption, distribution, or elimination as a consequence of aging.

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ADVERSE REACTIONS

Combining DESMOPRESSIN ACETATE with other drugs or treatments can have an additive or synergistic effect. Laboratory tests for assessing patient status include levels of factor VIII coagulant and factor VIII von Willebrand factor (fVIII:vWF) as well as activated partial thromboplastin time. Factor VIII coagulant activity should be determined before and after administration of hemostasis factors. If factor VIII coagulant activity is present at the beginning of therapy and DESMOPRESSIN ACETATE is not to be relied on.

von Willebrand's Disease: Desmopressin acetate-von Willebrand disease: Factor VIII levels greater than 5%. DESMOPRESSIN ACETATE will often maintain hemostasis in patients with hemophilia A.

Hemophilia A: DESMOPRESSIN ACETATE 4 mcg/mL is administered as a sterile solution in cartons of ten 1 mL single-dose ampules (NDC 69918-899-10) and in 10 mL multiple-dose vials (NDC 69198-801-10), each containing 4.0 mcg DESMOPRESSIN ACETATE per mL.

No significant interactions have been observed with a variety of drugs that may be administered concurrently, including anticoagulants, corticosteroids, diuretics, aspirin, and other nonsteroidal anti-inflammatory drugs. Rare reports of thrombotic events (acute cerebrovascular thrombosis, acute myocardial infarction) have included evidence of arterial or venous thrombosis and have been reported in patients predisposed to thrombus formation, and rarely reports of hyponatremic convulsions have been reported with repeated dose administration.

OVERDOSAGE

The usual dosage range in adult patients with severe renal impairment. (See CONTRAINDICATIONS.)

Hemophilia A: DESMOPRESSIN ACETATE Injection is contraindicated in patients with hyponatremia or a history of hyponatremia.

Drug Interactions:
Several publications of desmopressin acetate’s use in the management of diabetes insipidus during pregnancy are available; these include a few anecdotal reports of congenital anomalies and low birth weight babies. However, no causal connection between these events and desmopressin acetate has been established. A fifteen year, Swedish epidemiological study of the use of desmopressin acetate in pregnant women revealed desmopressin acetate found the rate of birth defects to be no greater than that in the general population; however, the statistical power of this study is low. As opposed to preparations containing natural hormones, desmopressin acetate in antidiuretic doses has no uterine action and the physician will have to weigh the therapeutic advantages against the possible risks in each case.

Nursing Mothers:
Each mL provides: Desmopressin acetate 4.0 mcg

DESMOPRESSIN ACETATE Injection 4 mcg/mL contains as active substance, desmopressin acetate, a synthetic analogue of the natural hormone arginine vasopressin. One mL (4 mcg) of DESMOPRESSIN ACETATE (desmopressin acetate) solution has an antidiuretic activity of 4 mcg/mL is provided as a sterile, aqueous solution for injection.