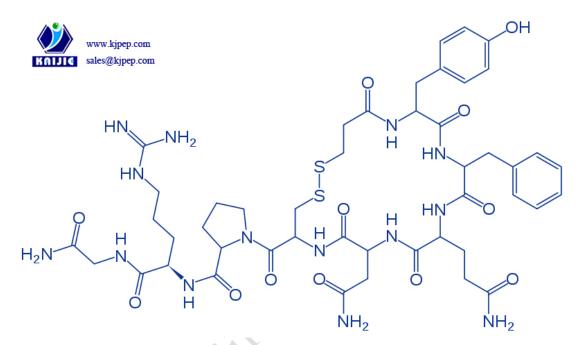


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About Author

Chengdu Kaijie Biopharm Co, Ltd. (KJBP) is one of leading peptide manufacturers in Asia. With its highest capacity of production in China and the outstanding quality of peptide products, Kaijie holds a unique position.

Desmopressin



1. US Trade Names: DDAVP, DDAVP Rhinal Tube , Minirin , Stimate

2. How Supplied

2.1.Generic

Injection Solution: 4 MCG/ML

Nasal Solution: 0.01 %

Nasal Spray: 0.01 MG/Actuation Oral Tablet: 0.1 MG, 0.2 MG

2.2.DDAVP

Injection Solution: 4 MCG/ML Nasal Spray: 0.01 MG/Actuation Oral Tablet: 0.1 MG, 0.2 MG

2.3.DDAVP Rhinal Tube

Nasal Solution: 0.01 %

2.4.Minirin

Nasal Spray: 0.01 MG/Actuation



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2.5.Stimate DS

Nasal Spray: 0.15 MG/Actuation

2.6.Stimate

Nasal Spray: 0.15 MG/Actuation

3.Adult Dosing

Intranasal formulations are not indicated for the treatment of primary nocturnal enuresis (PNE) due to a increased risk of hyponatremia, which can result in seizure and death.

Desmopressin acetate solution for injection: 4 micrograms is equivalent in antidiuretic activity to 16 international units of vasopressin. One microgram of desmopressin acetate is equivalent to 4 international units of vasopressin.

Desmopressin acetate nasal spray: one compression delivers 0.1 mL (10 mcg) per spray equivalent to 40 international units of vasopressin. Each 1 mL of intranasal solution has an antidiuretic activity of 400 international units .

Desmopressin acetate rhinal tube: 1 mL (0.1 mg) is equivalent to antidiuretic activity of 400 international units of vasopressin. Each 10 mcg of desmopressin is equivalent to 40 international units of vasopressin.

Hemophilia A, With factor VIII levels greater than 5%: 0.3 mcg/kg diluted in 50 mL sterile physiological saline, infused IV slowly over 15 to 30 minutes; monitor patient to determine necessity of further doses, tachyphylaxis may occur if given more often than every 48 hours Neurohypophyseal diabetes insipidus: 10 to 40 mcg/day (0.1 mL to 0.4 mL) INTRANASALLY, either as a single dose or 2 to 3 divided doses.

Neurohypophyseal diabetes insipidus: 2 to 4 mcg/day IV or SUBQ in 2 divided doses; comparable antidiuretic dose of the injection is about one-tenth (1/10) the intranasal dose

Neurohypophyseal diabetes insipidus: initial, 0.05 mg (one-half of the 0.1 mg tablet) ORALLY twice daily; maintenance 0.1 to 0.8 mg/day in divided doses.

Primary nocturnal enuresis: initial, 0.2 mg ORALLY at bedtime; dose may be titrated up to 0.6 mg if necessary



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von Willebrand disease type 1 (Mild to Moderate), With factor VIII levels greater than 5%: 0.3 mcg/kg diluted in 50 mL sterile physiological saline, infused IV slowly over 15 to 30 minutes; monitor patient to determine necessity of further doses, tachyphylaxis may occur if given more often than every 48 hours

4.Pediatric Dosing

Intranasal formulations are not indicated for the treatment of primary nocturnal enuresis (PNE) due to a increased risk of hyponatremia, which can result in seizure and death

Safety and efficacy of desmopressin acetate injection for the treatment of Hemophilia A and von Willebrand's disease (Type I) have not been established in infants less than 3 months old Safety and efficacy of desmopressin acetate injection for the treatment of diabetes insipidus have not been established in children less than 12 years of age

Desmopressin acetate solution for injection: 4 micrograms is equivalent in antidiuretic activity to 16 international units of vasopressin. One microgram of desmopressin acetate is equivalent to 4 international units of vasopressin.

Desmopressin acetate nasal spray: one compression delivers 0.1 mL (10 mcg) per spray equivalent to 40 international units of vasopressin. Each 1 mL of intranasal solution has an antidiuretic activity of 400 international units of vasopressin.

Desmopressin acetate rhinal tube: 1 mL (0.1 mg) is equivalent to antidiuretic activity of 400 international units of vasopressin. Each 10 mcg of desmopressin is equivalent to 40 international units of vasopressin.

Hemophilia A, With factor VIII levels greater than 5%: 3 months of age and older; 0.3 mcg/kg diluted in sterile physiological saline, infused IV slowly over 15 to 30 minutes; dilute in 50 mL for children over 10 kg and in 10 mL for children 10 kg or less; monitor patient to determine necessity of further doses; tachyphylaxis may occur if given more often than every 48 hours

Neurohypophyseal diabetes insipidus: 3 months to 12 years; 5 to 30 mcg (0.05 mL to 0.3 mL) INTRANASALLY, either as a single dose or 2 to 3 divided doses; for doses less than 10 mcg use the rhinal tube system

Neurohypophyseal diabetes insipidus: 13 years and older; 10 to 40 mcg/day (0.1 mL to 0.4 mL) INTRANASALLY, either as a single dose or 2 to 3 divided doses.



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Neurohypophyseal diabetes insipidus: 12 years and older; 2 to 4 mcg/day IV or SUBQ in 2 divided doses; comparable antidiuretic dose of the injection is about one-tenth (1/10) the intranasal dose

Neurohypophyseal diabetes insipidus: 4 years and older; initial, 0.05 mg (one-half of the 0.1 mg tablet) ORALLY twice daily; maintenance, 0.1 to 0.8 mg/day in divided doses

Primary nocturnal enuresis: 6 years of age and older: initial, 0.2 mg ORALLY at bedtime, dose may be titrated up to 0.6 mg if necessary.

von Willebrand disease type 1 (Mild to Moderate), With factor VIII levels greater than 5%: 3 months and older: 0.3 mcg/kg diluted in sterile physiological saline, infused IV slowly over 15 to 30 minutes; dilute in 50 mL for children over 10 kg and in 10 mL for children 10 kg or less; monitor patient to determine necessity of further doses, tachyphylaxis may occur if given more often than every 48 hours

5. Dose Adjustments

Acute illness: treatment for primary nocturnal enuresis with desmopressin acetate oral tablets should be interrupted during acute illnesses that may lead to fluid and/or electrolyte imbalances such as fever, recurrent vomiting or diarrhea, or vigorous exercise.

6. Mechanism of Action

Desmopressin acetate is a synthetic analogue of the naturally occurring hormone 8-arginine vasopressin (ADH) and an antidiuretic hormone that affects conservation of water in the kidneys. It has lesser vasopressor activity and action on visceral smooth muscles relative to the enhanced antidiuretic activity. Also, desmopressin acetate is more potent than arginine vasopressin in increasing plasma levels of factor VIII activity in hemophilic individuals and patients with von Willebrand's disease type I .

7. Absorption

Intranasal, oral: time to peak concentration, 0.9 h to 1.5 h

Bioavailability: (Oral, tablet), 0.16%, about 5% compared to intranasal

8. Elimination Half Life

(Oral), 1.5 h to 2.5 h

(IV, Intranasal), 75.5 min

9. Adverse Effects

Dermatologic: Flushing

Gastrointestinal: Nausea, Will respond to dosage decrease

Neurologic: Fatigue (10%), Headache (22.5%)