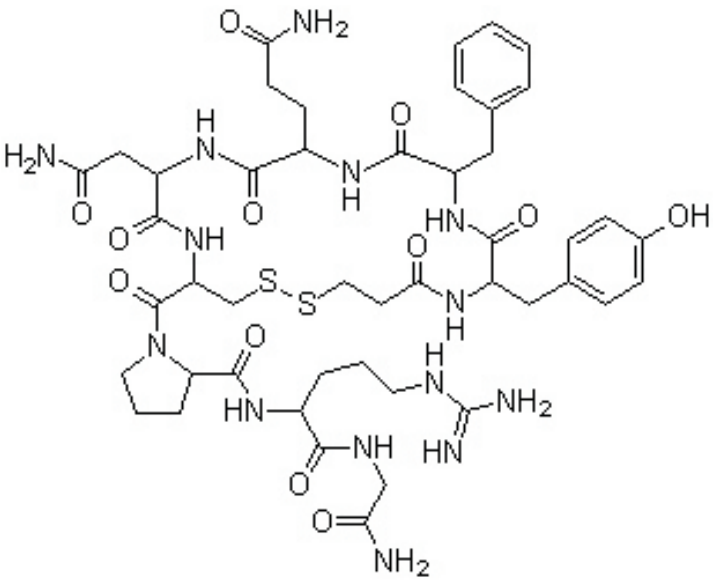
Taj Pharmaceuticals Ltd.

Desmopressin Monoacetate

CAS No. : 62288-83-9

Molecular Structure

Molecular Formula C46H64N14O12S2
Molecular Weight 1069.22
CAS Number 62288-83-9
EINECS 240-726-7



Mpr-Tyr-Phe-Gln-Asn-Cys-Pro-D-Arg-Gly-NH_2

Pharmacokinetic data

Bioavailability Variable; 0.08–0.16% (oral)
Protein binding 50%
Metabolism ?
Half life 1.5–2.5 hours
Excretion Renal
Therapeutic considerations
Pregnancy cat.
B2(AU) B(US)
Legal status
POM(UK) ℞-only(US)
Routes IV, IM, SC, intranasal, oral

DOSAGE

Take this by mouth as directed. Your dose and the frequency with which you take this will be based on your condition and response. Do not increase the dose, take this more often or stop taking this medication without first consulting your doctor. Limit drinking of water or other fluids while using this medication.

Adults and Children: It is recommended that patients be started on doses of 0.05 mg (1/2 of the 0.1 mg tablet) two times a day and individually adjusted to their optimum therapeutic dose. Most patients in clinical trials found that the optimal dosage range is 0.1 mg to 0.8 mg daily, administered in divided doses. Each dose should be separately adjusted for an adequate diurnal rhythm of water turnover. Total daily dosage should be increased or decreased in the range of 0.1 mg to 1.2 mg divided into two or three daily doses as needed to obtain adequate antidiuresis. See Pediatric Use subsection for special considerations when administering desmopressin acetate to pediatric diabetes insipidus patients.

SIDE EFFECTS

headaches
facial flushing
nausea
hyponatremia

Headache, nausea, mild stomach cramps and flushing may occur. If any of these effects persist or worsen, inform your doctor. Notify your doctor if you experience: headache, sudden weight gain, seizures. In the unlikely event you have an allergic reaction to this drug, seek immediate medical attention. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

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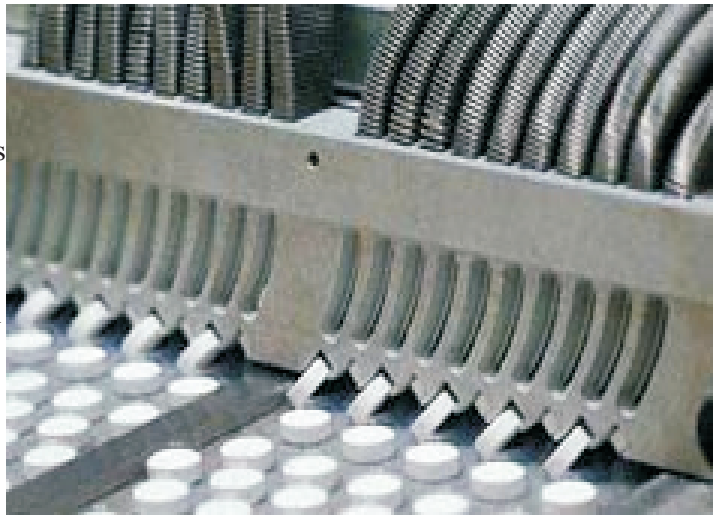
PRECAUTIONS



Intranasal formulationsat high doses and Injection have infrequently produced a slight elevation of blood pressure which disappears with a reduction of dosage. Although this effect has not been observed when single oral doses up to 0.6 mg have been administered, the drug should be used with caution in patients with coronary artery insufficiency and/or hypertensive cardiovascular disease, because of a possible rise in blood pressure.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 these patients are prone to hyponatremia.Rare severe allergic reactions have been reported

Nursing Mothers: There have been no controlled studies in nursing mothers. A single study in postpartum women demonstrated a marked change in plasma, but little if any change in assayablein breast milk following an intranasal dose of 0.01 mg.It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DDAVP is administered to nursing mothers.Pediatric Use: Central Diabetes Insipidus:have been used safely in pediatric patients, age 4 years and older, with diabetes insipidus for periods up to 44 months. In younger pediatric patients the dose must be individually adjusted in order to prevent an excessive decrease in plasma osmolality leading to hyponatremia and possible convulsions; dosing should start at 0.05 mg (1/2 of the 0.1 mg tablet). Use of in pediatric patients requires careful fluid intake restrictions to prevent possible hyponatremia and water intoxication. Fluid restriction should be discussed with the patient and/or guardian

INTERACTION

Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. Do not start, stop, or change the dosage of any medicine before checking with your doctor or pharmacist first.

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: chlorpromazine, chlorpropamide, clofibrate, demeclocycline, drugs that increase blood pressure (e.g., dopamine, epinephrine, ephedrine, norepinephrine), fludrocortisone, heparin, lithium, narcotic pain relievers (e.g., codeine), nonsteroidal anti-inflammatory drugs (e.g., celecoxib, ibuprofen, naproxen), oxybutynin, anti-seizure drugs (e.g., carbamazepine, lamotrigine), SSRI antidepressants (e.g., fluoxetine, sertraline), tricyclic antidepressants (e.g., amitriptyline, imipramine), urea, "water pills" (diuretics such as furosemide, hydrochlorothiazide), alcohol use.

Ask your doctor how much alcohol you may drink, if any. Alcohol interferes with desmopressin by increasing urination.

This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

DRUG DESCRIPTION

Desmopressin is a synthetic replacement for antidiuretic hormone, the hormone that reduces urine production during sleep. It may be taken nasally, intravenously, or as a pill. Doctors prescribe Desmopressin most frequently for treatment of diabetes insipidus or bedwetting.

In December 2007, US drug regulators banned using desmopressin nasal sprays for treating bedwetting, but said that desmopressin pills are still a safe bedwetting treatment for otherwise healthy patients. The regulators reviewed the drug after two patients using desmopressin nasal sprays died from hyponatremia, an imbalance of sodium levels in the body.

This medication is used to treat diabetes insipidus, for surgical procedures, head injury or other conditions requiring fluid control.

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
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