VASOPRESSIN INJECTION USP
20IU/ML
TAJ PHARMA

1. NAME OF THE MEDICINAL PRODUCT

Vasopressin Injection USP 20IU/ml Taj Pharma

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Injection contains:
Vasopressin……20IU

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

Clear, sterile solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For use in diabetes insipidus, when this is not of nephrogenic origin and control of bleeding from oesophageal varices.

4.2 Posology and method of administration

Posology

Adults

Diabetes Insipidus:

A dose of 0.25ml to 1ml (5 to 20 units) by subcutaneous or intramuscular injection every four hours.

Oesophageal Varices:

For the initial control of variceal bleeding Vasopressin should be given intravenously. Vasopressin, 20 units diluted in 100ml dextrose 5% w/v may be infused over a 15 minute period.

Elderly (over 65 years)

As for adults, no clinical or pharmacokinetic data specific to this age group are available. However, the drug has been successfully used at normal dosage in the elderly.

Paediatric population

Not recommended in children below 18 years.

Method of administration

Subcutaneous, intravenous or intramuscular injection.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Anaphylaxis to the active substance or to the excipients listed in section 6.1.

Patient with coronary artery disease or those intended to receive halogenated anaesthetic agents.

Chronic nephritis with nitrogen retention contraindicates the use of Vasopressin 20 International Units /ml injection until reasonable nitrogen blood levels have been attained.

Vascular disease (especially disease of coronary arteries), chronic nephritis (until reasonable blood nitrogen concentrations attained).

4.4 Special Warnings and precautions for use

This drug should not be used in patients with systemic hypertension or vascular disease, especially disease of the coronary arteries, except with extreme caution. In such patients, even small doses may precipitate pain, and with larger doses, the possibility of myocardial infarction should be considered. If this drug must be used in patients with peripheral vascular disease then the skin

should be observed carefully for signs of ischaemia.

Vasopressin may produce water intoxication. The early signs of drowsiness, listlessness and headaches should be recognised to prevent terminal coma and convulsions.

Adjustment of dosage in cases immediately post-hypophysectomy should be controlled on the basis of measurements of urine osmolality.

Vasopressin should be used cautiously in the presence of epilepsy, migraine, asthma, heart failure or any state in which a rapid addition to extracellular water may produce hazard for an already overburdened system.

Regular monitoring of blood urea nitrogen (BUN) levels is required in patients with chronic nephritis to ensure an adequate level is maintained (see section 4.3).

4.5 Interaction with other medicinal products and other forms of interaction

The following drugs may potentiate the antidiuretic effect of vasopressin when used concurrently: carbamazepine, chlorpropamide, clofibrate, fludrocortisone, urea or tricyclic antidepressants.

The following drug may decrease the antidiuretic effect of vasopressin when given concurrently: demeclocycline, noradrenaline, lithium, heparin, alcohol.

Ganglion blocking agents may produce a marked increase in sensitivity to the pressor effect of vasopressin.

4.6 Fertility, Pregnancy and lactation

Pregnancy

No animal reproduction studies on Vasopressin are available.

Oxytocic effect in third trimester has been reported. However, Vasopressin has been used successfully during pregnancy for the treatment of diabetes insipidus with no adverse effects on the foetus being reported. Nevertheless, as with all medicines, use during pregnancy should be avoided if possible and the potential benefit to the patient weighed against any possible risk to the foetus.

Breast-feeding

Vasopressin has been administered to breast-feeding women without apparent adverse effect on the infant.

4.7 Effects on ability to drive and use machines

Vasopressin can have an influence on driving as it may cause vertigo (see section 4.8).

4.8 Undesirable Effects

The following undesirable effects have been observed and reported during treatment with Vasopressin with the following frequency:

Not known – cannot be estimated from the available data.

Immune system disorders

• Hypersensitivity

• Anaphylaxis

Metabolism and nutrition disorders

• Hyper hydration/ water intoxication

Nervous system disorders

• Headache

• Vertigo

• Tremor

Cardiac disorder

• Chest pain due to angina

• Cardiac arrest

Vascular disorders

• Peripheral ischaemia

• Pallor

• Hypertension

Respiratory, thoracic and mediastina disorders

• Bronchospasm

Gastrointestinal disorders

• Flatulence

• Nausea

• vomiting

• diarrhea

• Abdominal pain

Skin and subcutaneous tissue disorders

• Gangrene

• Hyperhidrosis

• urticaria

Renal and urinary disorders

• Fluid retention

General disorders and administration site conditions

• Non-cardiac chest pain

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

If water intoxication occurs, no fluids should be given. In severe cases, small amounts of hypertonic saline may be administered. Urea and mannitol infusions may be helpful in cases of cerebral oedema. If a patient should experience anginal pain after administration of Vasopressin, amyl nitrite by inhalation or glyceryl trinitrate sublingually, may be given.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vasopressin and analogues

Mechanism of action

The antidiuretic action of Vasopressin is ascribed to increase in reabsorption of water by the renal tubules. Vasopressin can cause contraction of smooth muscle of the gastrointestinal tract, gall bladder, urinary bladder and all parts of the vascular bed, especially the capillaries, small arterioles and venules with less effect on the smooth musculature of the large veins. The direct effect on the contractile elements is neither antagonised by adrenergic blocking agents nor prevented by vascular denervation.

5.2 Pharmacokinetic properties

Absorption

Following subcutaneous or intramuscular administration of Vasopressin injection, the duration of antidiuretic activity is variable, but effects are usually maintained for 2-8 hours.

Biotransformation

The majority of the dose of Vasopressin is metabolised and rapidly destroyed in the liver and kidneys. Vasopressin has a plasma half-life of about 10 to 20 minutes.

Elimination

Approximately 5% of a subcutaneous dose of Vasopressin is excreted unchanged in the urine four hours after dosing.

5.3 Preclinical safety data

Preclinical safety data does not add anything of further significance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glacial acetic acid, water for injection

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in a refrigerator (2°C and 8°C). Do not freeze.

Keep the ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

Clear OPC/blue glass ampoules with white and blue rings above the OPC.

The white and blue rings are for product identification and should not be taken as break rings. The ampoules should be open cut at the OPC

Available in packs of 10 x1ml ampoules.

6.6 Special precautions for disposal and other handling

For single use only.

If only part used, discard the remaining solution.

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MANUFACTURED IN INDIA BY:

TAJ PHARMACEUTICALS LTD.
Mumbai, India
Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at:Gujarat, INDIA.
Customer Service and Product Inquiries:
1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)
Monday through Saturday 9:00 a.m. to 7:00 p.m. EST
E-mail: tajgroup@tajpharma.com