

NEW ZEALAND DATA SHEET

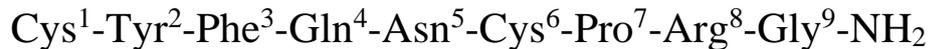
PITRESSIN®

Vasopressin injection (20 pressor units/mL)

NAME OF THE MEDICINE

Pitressin.

Pitressin is a sterile, aqueous solution of synthetic vasopressin (8-arginine vasopressin).



Vasopressin injection, 20 pressor unit per mL in 1 mL vials in multiple of 5 vials. CAS No: 113-79-1

DESCRIPTION

Vasopressin is a polypeptide hormone having the properties of causing the contraction of vascular and other smooth muscles and of antidiuresis. Each 1 mL vial of Pitressin (vasopressin injection), contains vasopressin (20 pressor units), acetic acid and chlorbutol 0.5% w/v as preservative.

Empirical Formula: C₄₃H₆₅O₁₂S₁₂

MW: 1084.24

PHARMACOLOGY

The antidiuretic action of Pitressin is ascribed to its ability to increase resorption of water by the renal tubules.

Pitressin can cause contraction of smooth muscle of the gastrointestinal tract and of 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.

Pharmacokinetics

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

The majority of a 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. Approximately 5% of a subcutaneous dose of vasopressin is excreted in urine unchanged after four hours.

INDICATIONS

Pitressin is indicated for prevention and treatment of post-operative abdominal distention in abdominal radiography to dispel interfering gas shadows and in diabetes insipidus.

CONTRAINDICATIONS

Pitressin is contraindicated in patients who are hypersensitive to the medicine.

Chronic nephritis with nitrogen retention contraindicates the use of vasopressin until reasonable nitrogen blood levels have been attained.

WARNINGS

This medicine should not be used in patients with vascular disease, especially disease of the coronary arteries, except with extreme caution. In such patients even small doses may precipitate anginal pain and with larger doses the possibility of myocardial infarction should be considered.

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

Vasopressin should not be administered intravenously; subcutaneous or intramuscular dosage should not exceed 0.75 mL.

PRECAUTIONS

Pitressin should be used cautiously in the presence of epilepsy, migraine, asthma, toxæmia of pregnancy, nephritis with arterial hypertension, goitre with cardiac complications, coronary thrombosis, angina pectoris and arteriosclerosis or any state in which a rapid addition to extracellular water may produce hazard for an already overburdened system.

Use in Pregnancy

Category B2: Use in pregnancy is not recommended. Medicines taken by only a limited number of pregnant women and women of child-bearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed.

Use in Lactation.

Use in lactation is not recommended. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage. It is not known whether Pitressin will affect breast-feeding infants.

Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

INTERACTIONS WITH OTHER MEDICINES

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

The following medicines may decrease the antidiuretic effect of vasopressin when used concurrently: democlocycline, noradrenaline, lithium, heparin, alcohol.

Ganglionic blocking agents may produce a marked increase in sensitivity to the pressor effects of vasopressin.

Isolated cases of severe bradycardia and heart block have been reported in patients receiving vasopressin and H₂ antagonists.

ADVERSE EFFECTS

Local or systemic allergic reactions may occur in hypersensitive individuals. The following side effects have been reported following the administration of Pitressin: tremor, sweating, vertigo, circumoral pallor, 'pounding' in head, abdominal cramps, passage of gas, nausea, vomiting, urticaria, bronchial constriction, arrhythmias, decreased cardiac output, angina, myocardial ischaemia, peripheral vasoconstriction, gangrene, rhabdomyolysis and cutaneous gangrene. Anaphylaxis (cardiac arrest and/or shock) has been observed shortly after injection of Pitressin.

DOSAGE AND ADMINISTRATION

Intravenous use of Pitressin is NOT recommended. Subcutaneous or intramuscular dosage should not exceed 0.75 mL.

Dosage should be appropriately reduced in use in children.

Abdominal distention

In the average post-operative adult patient give 0.25 mL (5 units) by i.m. or s.c. initially, increasing to 0.5 mL (10 units) at subsequent injections if necessary. Injections may be repeated at three or four hourly intervals as required.

Pitressin used in this manner will frequently prevent or relieve post-operative distention. These recommendations apply also to distention complicating pneumonia or other acute toxaeemias.

Abdominal radiography

for the average case, two i.m. or s.c. injections of 0.5 mL each (10 units) are suggested. These should be given two hours and one half hour respectively before films are exposed. Many radiologists advise giving an enema prior to the first dose of Pitressin.

Diabetes insipidus

Pitressin may be given by i.m. or s.c. injection or administered intra nasally on cotton pledgets by nasal spray or by dropper. The dosage by injection is 0.25 to 0.5 mL (5 to

10 units) repeated two or three times daily as needed. When Pitressin is administered intranasally by spray or on pledgets, the dosage and interval between treatments must be determined for each patient.

OVERDOSE

An overdose may result in water intoxication (i.e. undue retention of water) with symptomatic hyponatremia or hypo-osmolality or both.

Symptoms:

Abdominal cramps, nausea, vomiting, dizziness, lethargy or oedema may be present. Severe water intoxication may produce convulsions or coma/

Treatment:

Symptomatic. Circulation, electrolytes and fluid balance should be closely monitored. Water intoxication may be treated with water restriction and temporary withdrawal of vasopressin until polyuria occurs. Severe water intoxication may require osmotic diuresis with mannitol, hypertonic dextrose, or urea alone or with furosemide.

PRESENTATION

Shelf life

24 months as packaged for sale.

Special Precautions for Storage

Store below 25°C in glass vials

Pitressin injection is packed in 1mL glass vials and packaged in multiple of 5 vials.

Medicine Schedule

Prescription medicine

SPONSOR DETAILS

Link Pharmaceuticals Ltd

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DATE OF PREPARATION

30 May 2014