

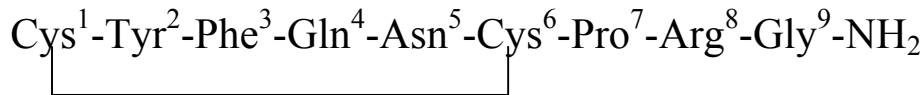
# PRODUCT INFORMATION

## Pitressin<sup>®</sup> Vasopressin Injection

(1 mL vials containing synthetic vasopressin (20 pressor units))

### PITRESSIN<sup>®</sup>

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



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<sup>®</sup> (vasopressin injection), contains vasopressin (20 pressor units) and chlorbutol 0.5% w/v as preservative.

Empirical Formula: C<sub>46</sub>H<sub>65</sub>N<sub>15</sub>O<sub>12</sub>S<sub>2</sub>

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.

## INDICATIONS

Pitressin is indicated for prevention and treatment of postoperative 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 drug. Chronic nephritis with nitrogen retention contraindicates the use of vasopressin until reasonable nitrogen blood levels have been attained.

## WARNINGS

This drug 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: 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.

Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.

### **Drug Interactions**

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

The following drugs 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 H<sub>2</sub> antagonists.

## **ADVERSE REACTIONS**

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 postoperative 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, postoperative distention. These recommendations apply also to distention complicating pneumonia or other acute toxæmias.

**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. injections or administered intranasally 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.

## **PRESENTATION**

Sterile injection containing vasopressin 20 pressor units/mL in 1 mL vial, . Also contains Acetic acid, Chlorbutol and water for injection.

Pitressin is supplied as pack of 5 x 1 mL vials

Poisons schedule: S4

TGA Approval: 21<sup>st</sup> November 2005

Date of most recent amendment: 26<sup>th</sup> Nov 2008

## **SPONSOR**

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