

SUMMARY OF PRODUCT CHARACTERISTICS

Product Summary

1. NAME OF THE MEDICINAL PRODUCT

Pitressins 20PU/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml contains 0.4 mg of Synthetic vasopressin (50 pressor unit per mg) which is equivalent to Pitressin 20 pressor units.

3. PHARMACEUTICAL FORM

Solution for injection

A clear, sterile, colourless 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

Subcutaneous, intravenous or intramuscular injection.

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 Pitressin should be given intravenously. Pitressin, 20 units diluted in 100ml dextrose 5% w/v may be infused over a 15 minute period. (Shields R, Britt J Hosp Med p.126, February 1977)

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 at normal dosage in the elderly.

Children and infants

Not recommended.

4.3 Contraindications

Anaphylaxis or hypersensitivity to the drug or its components.

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

Chronic nephritis with nitrogen retention contra-indicates the use of Pitressin until reasonable blood urea nitrogen levels have been 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.

Pitressin 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.

Pitressin 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.

4.5. Interaction with other medicinal products and other forms of Interactions

None Known

4.6. Pregnancy and Lactation

No animal reproduction studies on Pitressin are available.

Pitressin 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.

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

4.7. Effects on ability to drive and use machines

Pitressin may cause vertigo (see side effects).

4.8. Undesirable 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 the head, abdominal cramps, passage of gas, nausea, vomiting, urticaria, bronchial constriction. Anaphylaxis (cardiac arrest and/or shock) has been observed shortly after injection of Pitressin. Peripheral ischaemia and rarely gangrene have been reported following use of Pitressin.

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 Pitressin, amyl nitrite by inhalation or glyceryl trinitrate sublingually, may be given.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

The antidiuretic action of Pitressin is ascribed to increase in reabsorption of water by the renal tubules. Pitressin 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

Following subcutaneous or intramuscular administration of Pitressin injection, the duration of antidiuretic activity is variable, but effects are usually maintained for 2-8 hours. The majority of the dose of Pitressin is metabolised and rapidly destroyed in the liver and kidneys. Pitressin has a plasma half-life of about 10 to 20 minutes. Approximately 5% of a subcutaneous dose of Pitressin 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

Not known.

6.3. Shelf Life

24 months.

Once opened, use immediately.

6.4. Special precautions for storage

Store between 2°C and 8°C. Do not freeze.

6.5. Nature and contents of container

White neutral glass ampoules with two orange break bands. Available in packs of 10 x1ml ampoules. Glass ampoule Type I Ph.Eur (ampoule 1cc oil break type straight stem flint).

6.6. Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

None

7. Marketing Authorisation Holder

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8. Marketing Authorisation Number(s)

PA 899/1/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 April 1979/1 April 1999

10. DATE OF REVISION OF THE TEXT

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