

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

8-Arginine Vasopressin (Synthetic)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

8-Arginine Vasopressin (Synthetic)

3. PHARMACEUTICAL FORM

Bulk material (powder) for importation as a biological raw material.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules (PL 12762/0024)

4.2. Posology and Method of Administration

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

4.3 Contraindications

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

4.4. Special Warnings and Special Precautions for Use

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

4.5. Interactions with other Medicinal Products and other Forms of Interaction

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

4.6. Pregnancy and Lactation

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

4.7. Effects on Ability to Drive and Use Machines

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

4.8. Undesirable Effects

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

4.9. Overdose

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Vasopressin is a potent peripheral vasoconstrictor. Vasopressin has a direct action on the kidney. It also constricts peripheral vessels and causes contraction of the smooth muscle of the intestine, gall bladder and urinary bladder.

Due to rapid inactivation by a number of enzymes that cleave the peptide at several sites, the effects of vasopressin are relatively short lived unless given by continuous infusions.

5.2. Pharmacokinetic Properties

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

5.3. Pre-clinical Safety Data

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules.(PL 12762/0024)

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

None.

6.2. Incompatibilities

Not applicable, bulk material for importation as a biological raw material, (for manufacture of Pitressin ampoules. (PL 12762/0024)

6.3. Shelf Life

12 months.

6.4. Special Precautions for Storage

Store over a dessicant in a tightly closed glass container.

6.5. Nature and Contents of Container

Tightly closed flint glass bottle with a screw cap over dessicant of Drierite.

6.6. Instructions for Use/Handling

None

ADMINISTRATIVE DATA

7. MARKETING AUTHORISATION HOLDER

PL Holder Goldshield Pharmaceuticals Limited,
NLA Tower,
12-16 Addiscombe Road,
Croydon
CR0 0XT.

8. MARKETING AUTHORISATION NUMBER(S)

PL 12762/0018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

28 September 1998

10. DATE OF (PARTIAL) REVISION OF THE TEXT

December 1997.