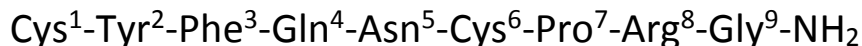


NEW ZEALAND DATA SHEET

1 PITRESSIN® 20 pressor units solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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



Argipressin is a polypeptide hormone having the properties of causing the contraction of vascular and other smooth muscles and of antidiuresis. Each 1mL ampoule contains 20 pressor units of argipressin.

CAS Number: 113-79-1

Molecular Formula: C₄₃H₆₅O₁₂S₁₂

Molecular Weight: 1084.24

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pitressin is supplied as a sterile clear and colourless solution for injection in 1mL glass ampoules, in a pack of 10 ampoules.

4 CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Dose and method of administration

Intravenous use of argipressin 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.

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

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 argipressin.

Diabetes insipidus

Argipressin 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 argipressin is administered intranasally by spray or on pledgets, the dosage and interval between treatments must be determined for each patient.

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4.3 Contraindications

Argipressin is contraindicated in patients who are hypersensitive to the medicine or any of the excipients.

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

4.4 Special warnings and precautions for use

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.

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

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

Precautions

Argipressin 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.

4.5 Interaction with other medicines and other forms of interaction

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

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

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

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

4.6 Fertility, pregnancy and lactation

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. It is not known whether Pitressin will affect breast-feeding infants.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

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Adverse Effects

Local or systemic allergic reactions may occur in hypersensitive individuals. The following side effects have been reported following the administration of argipressin: 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 argipressin.

4.9 Overdose

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

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 argipressin until polyuria occurs. Severe water intoxication may require osmotic diuresis with mannitol, hypertonic dextrose, or urea alone or with furosemide.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Argipressin 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.

5.2 Pharmacokinetic properties

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

The majority of a dose of argipressin is metabolised and rapidly destroyed in the liver and kidneys. Argipressin has a plasma half-life of about 10 to 20 minutes. Approximately 5% of a subcutaneous dose of argipressin is excreted in urine unchanged after four hours.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Inactive ingredients include Water for Injection q.s., and acetic acid.

6.2 Incompatibilities

None known.

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6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at 2-8°C. Refrigerate. Do not freeze. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Pitressin is a sterile injection containing argipressin 20 pressor units / mL in 1mL glass ampoule.

Pitressin is supplied as a pack of 10 x 1mL glass ampoules.

6.6 Special precautions for disposal <and other handling>

No special requirements.

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

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Link Pharmaceuticals Ltd.

Level 31, Vero Centre

48 Shortland Street

Auckland 1140

NEW ZEALAND

Tel: +64 9 358 7146

9 DATE OF FIRST APPROVAL

31 December 1969

10 DATE OF REVISION OF THE TEXT

26 July 2018

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Reformat of data sheet to new requirement.
All	Replace 'vasopressin' with 'argipressin' (AAN, BAN)
3 and 6.5	Replace primary pack vial with ampoule Replace pack size of 5 x 1mL vials with 10 x 1mL ampoules
6.1	Remove preservative chlorobutanol
6.4	Revise storage to 2-8°C (Refrigerate. Do not freeze)