

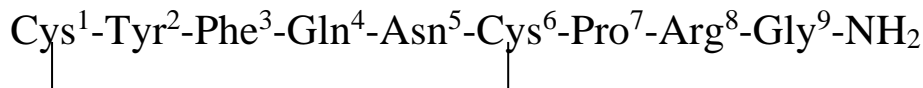
PRODUCT INFORMATION

Pitressin[®] Argipressin Injection (1 mL synthetic argipressin (20 pressor units) per ampoule)

NAME OF THE MEDICINE

PITRESSIN[®]

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



CAS Number: 113-79-1

DESCRIPTION

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, Water for Injection q.s., and acetic acid.

Molecular Formula: C₄₆H₆₅N₁₅O₁₂S₂

Molecular Weight: 1084.24

PHARMACOLOGY

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.

INDICATIONS

Pitressin is used in the prevention and treatment of postoperative abdominal distention; in abdominal radiography to dispel interfering gas shadows and in diabetes insipidus.

CONTRAINDICATIONS

Argipressin is contraindicated in patients who are hypersensitive to the drug or any of the excipients. Chronic nephritis with nitrogen retention contraindicates the use of argipressin 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.

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 0.75mL.

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.

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.

INTERACTIONS WITH OTHER MEDICINES

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

The following drugs 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.

ADVERSE REACTIONS

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.

DOSAGE AND 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 postoperative adult patient, give 0.25mL (5 units) by i.m. or s.c. initially, increasing to 0.5mL (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, 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 argipressin.

Diabetes insipidus: Argipressin 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 0.5mL (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.

OVERDOSAGE

For information on the management of overdose, contact the Poison Information Centre in Australia on 13 11 26 or in New Zealand on 0800 764 766.

PRESENTATION AND STORAGE CONDITIONS

Sterile injection containing argipressin 20 pressor units/mL in 1mL glass ampoule. Also contains Acetic acid, and Water for Injection.

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

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

NAME AND ADDRESS OF THE SPONSOR

In Australia :

Link Medical Products Pty. Ltd.
5 Apollo Street
Warriewood, 2102, NSW,
Australia.

In New Zealand :

Link Pharmaceuticals Ltd.,
Auckland, New Zealand.

POISONS SCHEDULE OF THE MEDICINE

S4 – Prescription Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

21st November 2005

DATE OF MOST RECENT AMENDMENT

9 June 2017

PITRESSIN

(Pi-TRES-sin), Argipressin

Consumer Medicine Information (CMI)

What is in this CMI

This CMI answers some of the common questions about PITRESSIN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the possible risks of taking PITRESSIN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medication. You may want to read it again.

What PITRESSIN is used for

PITRESSIN is a medicine that contains argipressin, or antidiuretic hormone.

Argipressin is normally produced by the pituitary gland.

Argipressin acts on blood vessels and the kidney and reduces the amount of fluids you pass in the urine. Argipressin also causes muscles called "smooth muscles" to contract.

If your body does not produce enough argipressin you can get a condition called "diabetes insipidus".

PITRESSIN is used to treat deficiency of argipressin in this disorder. Symptoms of diabetes insipidus include passing large volumes of pale urine and feeling extremely thirsty. Diabetes insipidus is not the same as diabetes mellitus where sugar is passed in the urine.

Argipressin can also be used by your doctor to relieve stomach bloating after you have had surgery or an X-ray procedure of the abdomen.

Ask your doctor if you have any questions why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason. There is no evidence that PITRESSIN is addictive.

This medicine is available only with a doctor's prescription.

Before you use PITRESSIN

When you must not use it

Do not use PITRESSIN if you have an allergy to:

- Any medicine containing argipressin
- Any of the ingredients listed at the end of this leaflet
- Any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath,
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use this medicine if you have chronic kidney problems.

Do not use this medicine if you have coronary artery disease. PITRESSIN may bring on angina pain or heart problems.

Do not use this medicine if you are pregnant. It is not known whether PITRESSIN will harm your baby.

Do not use this medicine if you are breastfeeding. Again it is not known whether PITRESSIN will affect your baby.

Do not use PITRESSIN after the expiry date printed on the pack or if packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start to use this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods preservative or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Asthma
- Blood vessel disease
- Swelling of thyroid glands with heart problems
- Heart Disease
- Kidney disease associated with high blood pressure
- Migraine
- Seizures (convulsions)
- Complications with a previous pregnancy

Tell your doctor if you are pregnant or intend to become pregnant. Tell your doctor if you plan to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start to use PITRESSIN.

Taking other medicines with PITRESSIN

Tell your doctor of pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PITRESSIN may interfere with each other. These include:

- Carbamazepine, a medicine used to treat epilepsy or convulsions
- Medicines called “tricyclic antidepressants” that are used to treat depression
- Heparin, a medicine used to thin the blood
- Fludrocortisone, a medicine used to treat Addison’s disease or conditions of insufficiency of body salt.
- Noradrenaline, a medicine used to treat very low blood pressure
- Urea, a medicine used to treat dry skin conditions
- Demeclocycline, a medicine used to treat certain infections
- Alcohol
- Lithium used to treat certain mood disorders
- Medicines called “H2 blockers” that are used to treat stomach ulcers by controlling stomach acid secretions.

These medicines may be affected by PITRESSIN, or may affect how well it works. You may need different amounts of your medicine, or

you may need to take different medicines.

Ask your doctor or pharmacist if you are unsure about any of these medicines, or are uncertain if you maybe taking any of these medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How to use PITRESSIN

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to use

Your doctor will tell you how much PITRESSIN to use. The instructions that follow are for the use of PITRESSIN in diabetes insipidus only. If you are given PITRESSIN for another condition your doctor or nurse will give you this medicine in a hospital or clinic.

The usual dose for diabetes insipidus is 0.25 mL to 0.5 mL repeated two or three times a day as instructed by your doctor.

How to use it

PITRESSIN is for injection into a muscle or under the skin, or through the nostrils using a spray, cotton wad (pledgets) or

a dropper. **If you have been instructed to give yourself PITRESSIN, make sure your doctor shows you how to use this medicine. Use exactly as directed by your doctor.**

Do not use more or less than the doctor has prescribed.

When to use it

Use your medicine at about the same time each day. Using PITRESSIN at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it

Continue to use your medicine for as long as your doctor tells you. This medicine helps you control your condition, but does not cure it. It is important to keep using your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (phone Australia 131 126 or New Zealand 0800 POISON or 0800 764 766) for advice or go to the Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much PITRESSIN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- Drowsiness
- Headache
- Listlessness
- Coma

While you are using PITRESSIN

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using PITRESSIN

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are using this medicine. It may affect other medicines used during

surgery.

If you become pregnant while using PITRESSIN, tell your doctor immediately.

Things you must not do

Do not take PITRESSIN to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give PITRESSIN to anyone else, even if they have the same condition as you.

Do not stop taking PITRESSIN, or lower the dosage, even if you are feeling better, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how PITRESSIN affects you.

Be careful when drinking alcohol while taking PITRESSIN. If you drink alcohol, the effects of PITRESSIN may be decreased.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using PITRESSIN.

All medicines can cause some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Belching, stomach gas
- Nausea
- Dizziness
- Vomiting
- Stomach pain or cramps
- Sweating
- Trembling
- Pale area around the mouth
- Palpitations

The above list includes most of the common side effects of your medicine.

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- Chest Pain
- Confusion
- Difficulty breathing, wheezing
- Difficulty passing urine
- Drowsiness
- Listlessness
- Pain, redness irritation or swelling at the injection site
- Rapid weight gain
- Seizures (convulsions)
- Severe or continuous headaches
- Skin rash, itching (hives)

The above list includes a list of serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything making you feel unwell.

Other side effects not listed above can occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress

After Using PITRESSIN

Storage

Keep PITRESSIN in its sealed vial until it is time to use it.

Keep PITRESSIN in the refrigerator (2-8°C).

Keep PITRESSIN in a dark place where it is protected from light.

Do not leave PITRESSIN in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking PITRESSIN, or the expiry date has passed, ask your pharmacist what to do with any PITRESSIN left over.

Product Description

What it looks like

PITRESSIN is a clear colourless solution sealed in 1mL glass ampoules.

Ingredients

Active Ingredients

Argipressin

Inactive Ingredients

Acetic Acid

Water for Injections

The argipressin in PITRESSIN is synthetic and not of animal origin.

Sponsor

In Australia:

Link Medical Products Pty Ltd.
5 Apollo Street,
Warriewood, NSW, 2102,
Australia

In New Zealand:

Link Pharmaceuticals Ltd.
Level 31 Vero Centre
48 Shortland Street
Auckland 1010 New Zealand

Australian Registration
Number AUST R 286437

Date of last amendment:
9 June 2017