PITRESSIN

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PITRESSIN?

PITRESSIN contains the active ingredient argipressin. PITRESSIN is used to treat deficiency of argipressin in diabetes insipidus. Argipressin can also be to prevent or relieve stomach bloating after you have had surgery or a radiation procedure of the abdomen.

For more information, see Section <u>1. Why am I using PITRESSIN?</u> in the full CMI.

2. What should I know before I use PITRESSIN?

Do not use if you have had an allergic reaction to argipressin or any of the ingredients listed at the end of the CMI.

Do not use if you have you have chronic kidney problems which has caused accumulation of nitrogen in the blood.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use PITRESSIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PITRESSIN and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use PITRESSIN?

- PITRESSIN is for injection into a muscle or under the skin, or through the nostrils using a spray, cotton wad (pledgets) or a dropper
- The usual dose for diabetes insipidus is 0.25 mL to 0.5 mL repeated two or three times a day. Your doctor will tell you how much PITRESSIN to use

More instructions can be found in Section <u>4. How do I use PITRESSIN?</u> in the full CMI.

5. What should I know while using PITRESSIN?

Things you should do	 If you become pregnant while using PITRESSIN, tell your doctor immediately Remind any doctor, dentist, pharmacist, surgeon or anaesthetist you visit that you are using PITRESSIN 	
Things you should not do	• Do not stop using this medicine suddenly or change the dosage without checking with your doctor	
Driving or using machines	Be careful before you drive or use any machines until you know how PITRESSIN affects you	
Drinking alcohol	Be careful when drinking alcohol while taking PITRESSIN. Alcohol may decrease the effects of PITRESSIN	
Looking after your medicine	 Keep PITRESSIN in the refrigerator (2-8°C), in a dark place, protected from light, where children cannot reach it 	
	• Do not leave it in a car, on window sills, near a sink or in the bathroom.	
	 Keep PITRESSIN in its sealed vial until it is time to use it 	

For more information, see Section <u>5. What should I know while using PITRESSIN?</u> in the full CMI.

6. Are there any side effects?

If you get any of the following side effects, tell your doctor immediately or go to Accident and Emergency at your nearest hospital: chest pain, confusion, difficulty breathing or 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 or itching (hives).

Tell your doctor if you notice any of the following and they worry you: belching or stomach gas, nausea, dizziness, vomiting, stomach pain or cramps, sweating, trembling, pale area around the mouth, palpitations.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

PITRESSIN (Pi-TRES-sin)

Active ingredient: argipressin

Consumer Medicine Information (CMI)

This leaflet provides important information about using PITRESSIN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PITRESSIN.

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.

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

Where to find information in this leaflet:

- 1. Why am I using PITRESSIN?
- 2. What should I know before I use PITRESSIN?
- 3. What if I am taking other medicines?
- 4. How do I use PITRESSIN?
- 5. What should I know while using PITRESSIN?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using PITRESSIN?

PITRESSIN contains the active ingredient 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 diabetes insipidus. 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 to prevent or relieve stomach bloating after you have had surgery or a radiation 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.

2. What should I know before I use PITRESSIN?

Warnings

Do not use PITRESSIN if:

- you have chronic kidney problems which has caused accumulation of nitrogen in the blood
- you have an allergy to argipressin, or any of the ingredients listed at the end of this leaflet
- Always check the ingredients to make sure you can use this medicine

Check with your doctor if you:

- have allergies to any other medicines, foods preservative or dyes
- have or have had any of the following medical conditions:
 - coronary artery disease. PITRESSIN may bring on angina pain or heart problems
 - asthma
 - blood vessel (vascular) disease
 - swelling of thyroid glands with heart problems
 - heart disease
 - kidney disease associated with high blood pressure
 - migraine
 - epilepsy or seizures (convulsions)
 - complications of pregnancy such as pre-eclampsia (high blood pressure)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

It is not known whether PITRESSIN will harm your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether PITRESSIN will affect your baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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
- tricyclic antidepressants such as amitriptyline, clomipramine, dosulepin, doxepin, imipramine and nortriptyline
- 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 fluid retention (oedema)
- demeclocycline, a medicine used to treat certain infections
- lithium, a medicine used to treat certain mood disorders
- H2 blockers that are used to treat stomach ulcers, such as famotidine and nizatidine

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PITRESSIN.

4. How do I use PITRESSIN?

How much to use

- 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
- Do not use more or less than the doctor has prescribed
- The above doses 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.

How to use PITRESSIN

- PITRESSIN is for injection into a muscle (intramuscular) or under the skin (subcutaneous), 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 or pharmacist shows you how to use this medicine.
- Always use exactly as directed by your doctor.

Continue to use PITRESSIN 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 use PITRESSIN

If you miss your dose at the usual time, and if it is almost time for your next dose, skip the dose you missed and take 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 take a double dose to make up for the dose you missed.

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

If you use too much PITRESSIN

If you think that you or anyone else may have used too much PITRESSIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

5. What should I know while using PITRESSIN?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using PITRESSIN.

Tell your doctor immediately if you:

Become pregnant while using PITRESSIN

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines until you know how PITRESSIN affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking PITRESSIN. Alcohol may decrease the effects of PITRESSIN.

Looking after your medicine

Keep PITRESSIN:

- in its sealed vial until it is time to use it
- in the refrigerator (2-8°C)
- in a dark place where it is protected from light

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- In the bathroom or near a sink, or
- In the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.,

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Gut and digestion-related: belching, stomach gas nausea vomiting stomach pain or cramps Heart-related: palpitations Other: dizziness sweating trembling facial flushing with a pale area around the mouth headache 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 Signs of an allergic reaction such as: difficulty breathing, wheezing pain, redness irritation or swelling at the injection site skin rash, itching (hives) Signs of fluid overload: drowsiness severe or continuous headaches listlessness Seizures (convulsions) Other: chest pain difficulty passing urine rapid weight gain confusion 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed above can occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

www.tga.gov.au/reporting-problems (in Australia) or https://nzphvc.otago.ac.nz/consumer-reporting/ (in New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What PITRESSIN contains

Active ingredient	argipressin
(main ingredient)	
Other ingredients	acetic acid
(inactive ingredients)	water for Injections

Do not take this medicine if you are allergic to any of these ingredients.

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

What PITRESSIN looks like

PITRESSIN is a clear colourless solution sealed in 1mL glass ampoules. (AUST R 286437).

Who distributes PITRESSIN

In Australia:

Link Medical Products Pty Ltd. 5 Apollo Street Warriewood, NSW, 2102 Australia Ph: 1800 181 060 linkhealthcare.com.au

In New Zealand:

Link Pharmaceuticals Ltd. Suite 38, Level 8 139 Quay Street Auckland 1010 New Zealand

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