

Package leaflet: Information for the patient

Argipressin 20 International Units/ml Solution for Injection

Argipressin

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

This product is known by the above name but will be referred to as Argipressin Injection throughout the rest of this leaflet.

What is in this leaflet

1. What Argipressin Injection is and what it is used for
2. What you need to know before you are given Argipressin Injection
3. How Argipressin Injection will be given to you
4. Possible side effects
5. How to store Argipressin Injection
6. Contents of the pack and other information

1. What Argipressin Injection is and what it is used for

Argipressin Injection contains argipressin which is similar to a naturally occurring hormone in your body. It is an 'antidiuretic' which helps to prevent excess loss of water in your urine and also narrows some blood vessels in the body.

Argipressin is used to treat:

- diabetes insipidus. This is a rare form of diabetes causing production of large quantities of urine. Argipressin increases the amount of water absorbed back into your kidneys
- bleeding from enlarged veins in the oesophagus (food pipe).

2. What you need to know before you are given Argipressin Injection

You should not be given Argipressin Injection:

- if you are allergic to argipressin or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from a severe allergic reaction (anaphylactic shock) to argipressin or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from any diseases or conditions associated with your blood vessels, especially the blood vessels of your heart.
- if you are intended to receive halogenated anaesthetic agents during surgical procedures
- if you suffer from a certain type of kidney disease called chronic nephritis with nitrogen retention (your doctor will advise you)

Speak to your doctor if one of these applies to you before you are given this medicine.

Warnings and precautions

Talk to your doctor or nurse before you are given Argipressin Injection:

- if you suffer from asthma or other allergic conditions
- if you suffer from migraine
- if you suffer from epilepsy (fits)
- if you suffer from high blood pressure, heart or kidney disease (you may need to have regular blood tests)
- if you suffer from obstruction of the blood vessels of the heart (e.g. coronary artery)
- if you have undergone removal of pituitary gland (dosage will depend on urine concentration).

Other medicines and Argipressin Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is extremely important because some medicines can strengthen or weaken the effects of others.

In particular, tell your doctor if you are taking any of the following:

- medicines which control seizures (carbamezepine)
 - other medicines to treat diabetes (chlorpropamide)
 - medicines used in corticosteroid replacement therapy (fludrocortisone)
 - medicines to treat depression (e.g. amitriptyline, imipramine etc.)
 - antibiotics (demeclocycline)
 - medicines which prevent blood clotting (heparin)
 - medicines used to treat mania (lithium)
 - medicines used for severe low blood pressure or cardiac arrest (noradrenaline)
 - medicines containing urea (in some skin and ear preparations)
 - lipid lowering agent (clofibrate)
- medicines which may be used in emergency for treating hypertension (hexamethonium)

Argipressin Injection with food, drink and alcohol

Do not drink alcohol before you are given Argipressin Injection.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse before you are given this medicine. As with all drugs, Argipressin should only be given in pregnancy and when breast-feeding if absolutely necessary. Your doctor will guide you.

Driving and using machines

Argipressin can affect your ability to drive and use machinery safely, as you may feel dizzy after receiving your injection. Speak to your doctor for further advice.

3. How Argipressin Injection will be given to you

It is most likely that you will be in hospital when you are given Argipressin.

The recommended dose is

For the treatment of diabetes insipidus: Injected under the skin or into a muscle every four hours. Your doctor will decide on the most suitable dose and way to give it to you depending on your symptoms.

For the treatment of bleeding in the oesophagus: The dose is diluted in a sugar solution and slowly dripped through a needle into a vein. Your doctor will decide on the most suitable dose and way to give it to you depending on your symptoms.

Use in children and adolescents

Argipressin is not recommended in children below 18 years

Elderly

No dose change, give as per adults.

If you think you have been given more Argipressin Injection than you should have

As the Injection will be administered by a doctor, it is unlikely that you will be given more than is necessary. However, if you think that you have been given too much, tell your doctor immediately. If you experience chest pain after receiving this medicine, inform your doctor immediately.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can sometimes cause side effects, although not everyone gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately as this can also result in a heart attack if not treated straight away.

Argipressin can cause 'water intoxication'. Signs of this are drowsiness, being uninterested in anything (listless) and headaches. If you notice any of these signs, tell

the nurse or your doctor straightaway. If it is not corrected, water intoxication can lead to fits or even coma.

Other side effects include:

Not known: frequency cannot be estimated from the available data

- Gangrene – with symptoms of redness, swelling, loss of sensation/severe pain which can cause dead, black areas of skin- in areas such as fingers or toes
- Decreased oxygen in a tissue – with symptoms of pain, pale skin, tingling skin (usually because of decreased blood flow)
- Nettle rash or hives – Itchy red bumps on the skin (urticaria)
- Repeated desire to pass stools (diarrhoea)
- Abnormal collection of fluid in the body or ‘bloating’
- High blood pressure
- Paleness of the lips
- Wheezing
- Dizziness
- Feeling sick or being sick
- Passing wind
- Pounding in the head or a headache
- Stomach ache
- Excessive sweating
- Shakiness

In patients with disease of the heart or circulation, Argipressin may give rise to angina (chest pain).

Reporting of side effects

If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Argipressin Injection

Keep this medicine out of the sight and reach of children.

The storage of Argipressin Injection will not be your responsibility.

Store in a refrigerator (2°C and 8°C). Keep the ampoules in the outer carton in order to protect from light. Do not freeze.

For single use only.

If only part used, discard the remaining solution.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Argipressin Injection contains

- The active substance is argipressin. Each 1 ml contains 20 international units argipressin (vasopressin) which is Equivalent to 0.4mg argipressin, based on 50 international units per mg).

- The other ingredients are glacial acetic acid and sufficient water for injections is used to make the final volume of 1ml.

What Argipressin Injection looks like and contents of the pack

Argipressin Injection is a clear, sterile solution. It is a solution for injection which comes in a small glass bottle (ampoule), containing 20 international units of the active ingredient, argipressin. Each ampoule has a blue OPC (one-point-cut) where the ampoule is opened and two (yellow and blue) product identification rings. It is available in packs of ten 1ml ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mercury Pharmaceutical Ltd, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom.

Manufacturer

Haupt Pharma Wülfing GmbH, Bethelner Landstraße 18, D-31028 Gronau, Germany

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