

Package leaflet: Information for the user

Argipressin AOP 20 IU/ml solution for injection

Argipressin

Read all of this leaflet carefully before you start using 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What is Argipressin AOP and what it is used for
2. What do you need to know before you use Argipressin AOP
3. How to use Argipressin AOP
4. Possible side effects
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1. What Argipressin AOP is and what it is used for

Argipressin AOP 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 use Argipressin AOP

Do not use Argipressin AOP:

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

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

Warnings and precautions

Special precautions for use of Argipressin is mandatory,

- 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
- if you suffer from obstruction of the blood vessels of the heart (e.g. coronary artery disease).
- if you have undergone removal of pituitary gland (dosage will depend on urine concentration).

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

Other medicines and Argipressin AOP

Tell your doctor or pharmacist if you are using or have recently used any other medicines, even if this involves over-the-counter pharmaceuticals. 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:

- medicine which control seizures (carbamazepine)
- medicine to treat diabetes (chlorpropamine)
- medicine used in corticosteroid replacement therapy (fludrocortisone)
- medicines to treat depression (e.g. amitriptyline, imipramine etc.)
- lipid lowering agent (clofibrate)
- medicines containing urea (in some skin and ear preparations)
- antibiotics (demeclocycline)
- medicine used for severe low blood pressure or cardiac arrest (noradrenaline)
- medicine used to treat mania (lithium)
- medicine which prevents blood clotting (heparin).

Argipressin AOP with food, drink and alcohol

Argipressin may not be used in combination with alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

No sufficient data is available which demonstrates the safety for use of Argipressin during pregnancy.

Whether Argipressin is excreted in human milk is not known. There is no evidence for an increased risk of injury to humans.

The use of Argipressin during pregnancy and during lactation is not recommended.

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.

Argipressin AOP contains less than 1 mmol of sodium (23 mg) per ml, i.e. essentially sodium-free.

3. How to use Argipressin AOP

Argipressin AOP will always be administered by a physician. It is most likely that you will be in hospital when you are given Argipressin.

For the treatment of diabetes insipidus: the dose is usually 0.25 ml to 1 ml injected under the skin or into a muscle every four hours.

For the treatment of bleeding in the oesophagus: the dose is usually 1 ml diluted in a sugar solution and slowly dripped through a needle into a vein. This will usually take about 15 minutes.

Your doctor will decide on the most suitable dose and way to give it to you depending on your symptoms.

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

Elderly (over 65 years)

The dose is the same as for adults.

Use in children

Not recommended in children below 18 years.

If you use more Argipressin AOP than you should

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 stop using Argipressin AOP

This medication will usually be administered by a physician. If you believe that the use of the medicine was stopped too early, talk to your doctor immediately. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. 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.

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 sometimes seen are:

- Dizziness
- Abnormal collection of fluid in the body leading to swollen face, swelling in hands and feet and weight gain
- Feeling sick or being sick or 'bloating'
- Diarrhoea
- Paleness of the lips, nail beds and tongue (pallor)
- Wind (flatulence)
- Wheezing
- 'Nettle rash' or hives - itchy red bumps
- Excessive Sweating
- Shakiness
- Gangrene which causes redness, swelling, loss of sensation/severe pain and dead black areas of skin like fingers or toes (very rare).
- Loss of sensation in fingers and toes
- Heart problems with slow or irregular heart beat
- Pounding in the head or a headache
- Stomach ache

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 pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via UK: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Argipressin AOP

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

Store in a refrigerator (2°C - 8°C). Do not freeze.

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 use this medicine if the solution is not clear and colourless.

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 AOP contains

The active substance is Argipressin. One ampoule with 1 ml solution for injection contains Argipressin, equivalent to 20 International Units (IU) of argipressin (as argipressin acetate).

The other excipients are sodium chloride, glacial acetic acid to adjust the pH value, water for injection.

What Argipressin AOP looks like and contents of the pack

Argipressin AOP 20 IU/ml solution for injection is a clear, colourless injection solution available as:

1 ml colourless ampoule with two blue colour code rings, containing 1 ml of solution.

Each pack contains 5, 10 or 50 ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

AOP Orphan Pharmaceuticals AG

Wilhelminenstraße 91/II f

1160 Vienna

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Manufacturer

Amomed Pharma GmbH

Storchengasse 1

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