PACKAGE LEAFLET: INFORMATION FOR THE USER

Desmopressin Acetate Tablets 100 & 200 microgram

The name of your medicine is Desmopressin acetate tablets, which will be referred to as 'Desmopressin' or 'Desmopressin tablets' throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

❶ What Desmopressin is and what it is used for

Desmopressin tablets are round, white tablets. They contain the active ingredient desmopressin acetate hydrate.

Desmopressin tablets are used for the treatment of:

- vasopressin-sensitive cranial diabetes insipidus (a disease causing the passing of excessive urine because not enough ADH [a hormone] is produced). Vasopressin-sensitive means that the disease can be treated with Desmopressin.
- post-hypophysectomy polyuria/polydipsia (frequent urination or excessive drinking following the removal of the pituitary gland).
- primary nocturnal enuresis (bed-wetting in a person who has never developed night-time bladder control).

❷ Before you take Desmopressin

Do not take Desmopressin tablets (and talk to your doctor) if you:

- are allergic (hypersensitive) to Desmopressin or any of the other ingredients of Desmopressin tablets (see list of ingredients in Section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- have heart disease or another condition that needs treatment with a diuretic (water tablet)
- have abnormal blood pressure and need treatment for bed-wetting
- drink a lot of fluid because of a mental condition
- abuse alcohol
- are over the age of 65 and need treatment for bed-wetting
- have low sodium levels
- have symptoms of ADH (antidiuretic hormone) disorder
- have an inherited sugar disorder (galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption)

Take special care with Desmopressin tablets (and talk to your doctor) if you:

- have a kidney disorder (you may need a larger dose)
- have heart disease
- have cystic fibrosis

Bed Wetting

If you are being treated with Desmopressin for bed-wetting, your fluid intake must be limited from 1 hour before until 8 hours after taking the tablets. You should avoid drinking water while swimming and you should stop taking Desmopressin if you are vomiting or have diarrhoea until your fluid balance is back to normal.

Fluid/Salt Disorder

You must be careful not to drink too much fluid if you have a condition that causes a fluid or salt disorder or if you are at risk of increased intracranial pressure (pressure on the brain).

It is important to monitor body weight and blood pressure during treatment with Desmopressin.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription. This is especially important of the following substances as they may interact with your Desmopressin tablets:

- antidepressants
- chlorpromazine (for mental illness)
- carbamazepine (for epilepsy)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen
- loperamide (for diarrhoea)

It may still be all right for you to be given Desmopressin and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or breast-feeding. Your doctor may want to monitor your blood pressure if you are pregnant.

Driving and using machines

Desmopressin has no effect on driving or using machines.

Important information about some of the ingredients of Desmopressin tablets

Desmopressin tablets contain **lactose**, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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❸ How you take Desmopressin

Dosage

Desmopressin tablets are taken by mouth.

Always take Desmopressin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Treatment of Diabetes Insipidus:

The starting dose in adults and children is 100 micrograms, three times daily. The dose should then be adjusted according to the patient's response.

For most patients, the adjusted dose is 100 to 200 micrograms, three times daily.

Post-hypophysectomy polyuria/polydipsia:

The dose of Desmopressin depends on the concentration of the urine.

Primary nocturnal enuresis:

The usual dose for children (from 5 years of age) and adults (up to 65 years of age) is 200 micrograms at bedtime. If necessary, your doctor may increase the dose to 400 micrograms.

The need for continued treatment should be reassessed after 3 months by stopping treatment with Desmopressin for at least one week.

If it appears that Desmopressin is not having an effect at low doses, your doctor may tell you not to take the tablets with food.

If you take more Desmopressin than you should

Go to the accident and emergency department at the nearest hospital straight away. Take the Desmopressin pack with you.

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

❹ Possible side effects

Like all medicines, Desmopressin tablets can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare.

Stop taking Desmopressin tablets and tell your doctor or go to the nearest hospital casualty department straight away if you experience any of the following:

- **An allergic reaction. The signs may include difficulty in breathing or swallowing, swelling of the lips, face, throat or tongue and a rash or itching (especially affecting the whole body).**

The following side effects have been reported:

- stomach pain
- nausea (feeling sick)
- abdominal (tummy) cramps
- vomiting
- headache
- allergic skin reactions
- more severe allergic reactions
- emotional disturbance in children (very rare)

Treatment with Desmopressin without reducing fluid intake may cause water retention or low sodium levels. **Low sodium levels can cause the following side effects:**

- headache
- nausea
- vomiting
- weight gain
- decreased sodium in the blood
- convulsions (fits – in serious cases)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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.

❺ How to store Desmopressin

Desmopressin tablets should be kept out of the sight and reach of children.

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

Store below 25°C. Store in the original package. Keep the bottle tightly closed. Keep the bottle in the outer carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer needed. These measures will help to protect the environment.

❻ Further information

What Desmopressin tablets contain

The active substance is desmopressin acetate hydrate. The other ingredients are: lactose monohydrate, potato starch, povidone, magnesium stearate and colloidal anhydrous silica.

What Desmopressin tablets look like and contents of the pack

30ml plastic bottles with a tamper-proof, twist-off cap and a silica gel desiccant insert. Each bottle contains either 30 or 90 tablets. The tablets are white, round and convex with break marks.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aspire Pharma Limited
Unit 4, Rotherbrook Court
Bedford Road
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Manufacturer

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