

Package leaflet: Information for the user

Desmopressin 60 micrograms sublingual tablets Desmopressin 120 micrograms sublingual tablets Desmopressin 240 micrograms sublingual tablets Desmopressin acetate

Read all of this leaflet carefully before you start taking 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 pharmacist.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Desmopressin sublingual tablets are and what they are used for
2. What you need to know before you take Desmopressin sublingual tablets
3. How to take Desmopressin sublingual tablets
4. Possible side effects
5. How to store Desmopressin sublingual tablets
6. Contents of the pack and other information

1. What Desmopressin sublingual tablets are and what it is used for

Desmopressin sublingual tablets contain 60, 120 or 240 micrograms of desmopressin (as acetate). This medicine belongs to a group of medicines called vasopressin and analogues; it is an antidiuretic i.e. it reduces urine production.

This medicine is used to treat:

- diabetes insipidus (extreme thirst and the continuous production of large volumes of dilute urine). This should not be confused with diabetes mellitus (sugar diabetes)
- post-hypophysectomy polyuria/polydipsia (extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland)

The 120 and 240 microgram tablets are also used to treat:

- primary nocturnal enuresis (bedwetting) in children (from 5 years of age) and adults (up to 65 years of age).

2. What you need to know before you take Desmopressin sublingual tablets

Do not take Desmopressin sublingual tablets if you:

- are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- have a serious heart or kidney disease
- are taking diuretics (water tablets)
- drink unusually large quantities of fluids, including alcohol
- under 5 or over 65 years old if taking this medicine for nocturnal enuresis (bedwetting)
- are taking medication for high blood pressure or have been told that your blood pressure is abnormal
- are suffering from habitual polydipsia (habitually increased fluid intake) or psychogenic polydipsia (mentally caused increased thirst and increased fluid intake)
- have low sodium levels in your blood (hyponatraemia)

- have conditions with increased ADH secretion (syndrome of inadequate ADH secretion)

You should avoid drinking large amounts of fluid while you are being treated with Desmopressin, as this could lead to a build-up of water which dilutes the salt in the body. This may lead to headaches, nausea/vomiting, weight gain and in severe cases convulsions.

Warnings and precautions

Talk to your doctor before using Desmopressin sublingual tablets:

- if you have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, systemic infections, fever or gastroenteritis
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance. A condition where your blood sodium levels are too low or you are likely to build up too much water in your body
- if you have cystic fibrosis
- if you have difficulty in passing water (severe bladder dysfunction).

While taking Desmopressin sublingual tablets for the treatment of primary nocturnal enuresis (bedwetting):

- fluid intake must be limited to a minimum from 1 hour before taking the dose at bedtime until the following morning (and, in any case, for at least 8 hours)
- stop taking this medicine when suffering from vomiting and/or diarrhoea until you are better
- swallowing water while swimming should be avoided because it could lead to a build-up of water in the body.

Children

This medicine is NOT suitable for children under 5 years of age when used to treat nocturnal enuresis (bedwetting).

Other medicines and Desmopressin sublingual tablets

Please inform your doctor or pharmacist if you:

- are taking or have recently taken or used any other medicines, even those not prescribed
- are on medication for depression, epilepsy or type II diabetes
- are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indometacin
- are taking a medicine containing loperamide for diarrhoea.

Desmopressin sublingual tablets with food and drink

The effect of this medicine may be decreased if the tablet is taken with a meal.

You should avoid drinking large amounts of fluid while you are being treated with this medicine.

Pregnancy and breastfeeding

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.

Blood pressure monitoring is recommended due to the increased risk of pre-eclampsia (a condition in pregnant women that can cause serious complications). Symptoms of pre-eclampsia include high blood pressure and oedema (swelling due to the build-up of fluid).

Driving and using machines

Desmopressin is unlikely to affect your ability to drive and use machines.

Desmopressin sublingual tablets contain lactose (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.

Desmopressin sublingual tablets contain sodium.

This medicine contains less than 1 mmol sodium (23 mg) per sublingual tablet, that is to say essentially 'sodium-free'.

3. How to take Desmopressin sublingual tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide on the appropriate dose to suit your condition.

How to take the tablets

This medicine is intended for sublingual use (under the tongue). The tablet should be placed under the tongue and allowed to dissolve. Do not swallow or chew or take with water.

Dosage

Diabetes insipidus:

A suitable starting dose in adults and children is one 60 microgram tablet taken sublingually (under the tongue) three times a day. The most common doses in adults and children are either one 60 microgram tablet or one 120microgram tablet taken sublingually (under the tongue) three times a day. The total daily dose normally lies in the range of 120 micrograms to 720micrograms

Post-hypophysectomy polyuria/polydipsia:

Your doctor will prescribe the most suitable dose for you based on the concentration of your urine.

Primary nocturnal enuresis (bedwetting)

The usual starting dose is one 120 microgram tablet taken sublingually (under the tongue) at bedtime. Depending on how well the bedwetting is controlled, your doctor may increase the dose to either two 120 microgram tablets or one 240 microgram tablets taken sublingually (under the tongue) at bedtime. The need for continued treatment is normally checked every three months.

If you take more Desmopressin sublingual tablets than you should

If you take more tablets than you should, talk to your doctor or pharmacist immediately.

If you forget to take Desmopressin sublingual tablets

Do not take a double dose to make up for a forgotten dose.

If you forget to take this medicine, please consult your doctor or pharmacist for advice.

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

4. Possible side effects

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

You should avoid drinking large amounts of fluid while you are being treated with Desmopressin, as this could lead to a build-up of water which dilutes the salt in the body. This is a serious problem and may lead to convulsions (fits).

STOP taking Desmopressin and contact your doctor or go to the nearest casualty department **immediately** if you experience any of the following side effects:

- unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea, vomiting, dizziness, feeling of general discomfort, memory impairment, feel a whirling or spinning sensation (vertigo) or falls
- allergic reactions including itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing

Common side effects may affect up to 1 in 10 people:

- headache

Uncommon side effects may affect up to 1 in 100 people:

- aggression
- emotional instability
- stomach pain
- nausea
- vomiting
- diarrhoea
- urinary symptoms
- swelling of the tissue in the lower limbs
- tiredness (fatigue)

Rare side effects may affect up to 1 in 1,000 people:

- symptoms of anxiety
- nightmares
- mood swings
- sleepiness (somnolence)
- high blood pressure
- irritability

Other side effects:

- low levels of sodium in the blood
- abnormal behaviour
- emotional disorder
- depression
- hallucination
- trouble sleeping
- increased restlessness and movement

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 at 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 Desmopressin sublingual tablets

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

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

Store in the original blister in order to protect from moisture. This medicine does not require any special temperature storage conditions.

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 Desmopressin sublingual tablets contain

- The active substance is desmopressin. Each tablet contains 60, 120 or 240 micrograms desmopressin (as desmopressin acetate)
- The other ingredients are lactose monohydrate, maize starch, citric acid (E 330), croscarmellose sodium (E 468) and magnesium stearate (E 470b)

What Desmopressin sublingual tablets look like and contents of the pack

The 60 microgram tablets are white or almost white, round, biconvex tablets debossed with 'I' on one side and plain on other side, with 6.5 mm diameter and 2 mm thickness.

The 120 microgram tablets are white or almost white, octagonal, biconvex tablets debossed with 'II' on one side and plain on other side, with 6.5 mm length/width and 2 mm thickness.

The 240 microgram tablets are white or almost white, square, biconvex tablets debossed with 'III' on one side and plain on other side, with 6 mm length/width and 2 mm thickness.

Each pack contains 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Aristo Pharma GmbH

Wallenroder Strasse 8-10

13435 Berlin

Germany

This leaflet was last revised in 11/2023.