



Package leaflet: Information for the user

Desmopressin 60 micrograms sublingual tablets, 120 micrograms sublingual tablets, 240 micrograms sublingual tablets

Desmopressin (as acetate)

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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Important things that you need to know:

- Desmopressin sublingual tablets are used to treat:
 - diabetes insipidus (a condition that causes extreme thirst and the continuous production of large volumes of dilute urine)
 - 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).
- You should avoid drinking large amounts of fluid while you are being treated with Desmopressin sublingual tablets, 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.
- If you experience unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting STOP USING Desmopressin sublingual tablets. You should tell your doctor immediately or go to the casualty department at your nearest hospital.

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 use Desmopressin sublingual tablets
3. How to use 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 they are used for

Desmopressin sublingual tablets are oral dispersible tablets. They look like tablets but are much softer and lighter. Intended for sublingual use (to be placed under the tongue where they will dissolve completely).

Desmopressin sublingual tablets are available in three strengths: 60, 120 or 240 micrograms. The tablets contain Desmopressin acetate, an antidiuretic (reduces urine production).

This medicine is used to treat:

- diabetes insipidus (extreme thirst and the continuous production of large volumes of dilute urine). IMPORTANT: 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 use Desmopressin sublingual tablets

There are general restrictions, precautions and warnings which apply to all patients using Desmopressin sublingual tablets.

General restrictions:

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
- are under 5 or over 65 years old, if taking the 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 sublingual tablets, 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 or pharmacist before taking Desmopressin sublingual tablets.

Take special care with Desmopressin sublingual tablets:

- if you have an illness causing fluid and/or salt 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

When Desmopressin sublingual tablets are taken together with food, the intensity and duration of effect may be reduced.

All patients, in case of children their parents and, where applicable, responsible nursing staff should be carefully instructed to adhere to the fluid instructions.

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. 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).

Desmopressin sublingual tablets contain lactose

Desmopressin contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to use Desmopressin sublingual tablets

INSTRUCTION FOR USE

Always take this medicine exactly as your doctor or pharmacist 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.

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.

If the tablet breaks into more than two pieces while you are taking the tablet out of the blister, do not take the broken pieces. Take a new tablet. The tablet will dissolve within 30 seconds.

Do NOT take more than the prescribed dose in any 24 hour period.

If you have the impression that the effect of Desmopressin is too strong or too weak, talk to your doctor or pharmacist.

Doses

Treatment of primary nocturnal enuresis (bedwetting)

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

Treatment of diabetes insipidus

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

Treatment of post hypophysectomy polyuria/polydipsia

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

If you take more of this medicine than you should

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

If you forget to take this medicine

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 medicine, 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 sublingual tablets, 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.

STOP USING Desmopressin sublingual tablets 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

If you experience any of the above side effects, you should contact your doctor or go to the nearest casualty department **immediately**.

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 (Oedema peripheral)
- tiredness (fatigue)

Rare side effects may affect up to 1 in 1000 people:

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

Other side effects:

- anaphylactic reactions (severe allergic reactions)
- low levels of sodium in the blood (hyponatraemia)
- abnormal behaviour
- emotional disorder
- depression
- hallucination
- trouble sleeping (Insomnia)
- increased restlessness and movement (psychomotor hyperactivity)

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 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 Desmopressin sublingual tablets out of the sight and reach of children.

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

Do not take this medicine after the expiry date on the packaging. 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 Desmopressin sublingual tablets contain

The active substance is: desmopressin acetate. It is available in three strengths: 60, 120 or 240 micrograms of desmopressin (as acetate).

The other ingredients are: lactose monohydrate, maize starch, citric acid anhydrous, croscarmellose sodium and magnesium stearate.

What Desmopressin sublingual tablets looks like and contents of the pack

Desmopressin 60 micrograms sublingual tablet

White or almost white, round, biconvex tablet debossed with “I” on one side and plain on other side, with 6.5mm diameter and 2mm thickness.

Desmopressin 120 micrograms sublingual tablet

White or almost white, octagonal, biconvex tablet debossed with “II” on one side and plain on other side, with 6.5mm length/width and 2mm thickness.

Desmopressin 240 micrograms sublingual tablet

White or almost white, square, biconvex tablet debossed with “III” on one side and plain on other side, with 6mm length/width and 2mm thickness.

The tablets are presented in:

- carton box containing OPA/Al/PVC/PE-Al blisters with integrated desiccant layer in pack sizes of 10, 20, 30, 60, 90 or 100 sublingual tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma Limited
Unit 4, Rotherbrook Court
Bedford Road, Petersfield, Hampshire
GU32 3QG, United Kingdom

Manufacturer

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OR

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This leaflet was last revised in January 2024

1010625-P1.7

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| Artwork for: | Aspire Pharma Limited |
| Product name: | Desmopressin 60/120/240 mcg sublingual tablets |
| Size: | X10 |
| PL/PA no: | PL35533/0200-0202 |
| Type: | Leaflet |
| Artwork dimensions: | 180mm x 600mm |
| Reason for request: | Initial artwork |
| Version no: | 1.7 |
| Date of revision: | 20.5.24 |
| Colours: | As swatches |
| Font(s): | Strada Pro 9pt |
| A/W software: | Indesign CC 2020 |



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