

180 mm

46.5 mm

90 mm

370 mm

Package Leaflet: Information for the user

Desmopressin 60 micrograms sublingual lyophilisate
Desmopressin 120 micrograms sublingual lyophilisate
Desmopressin 240 micrograms sublingual lyophilisate
Desmopressin (as 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, pharmacist 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Important things that you need to know:

- Desmopressin is 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).
You should avoid drinking large amounts of fluid while you are being treated with Desmopressin, as this could lead to a buildup 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. You should tell your doctor or immediately go to the casualty department at your nearest hospital.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine.

What is in this leaflet:

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

1. What Desmopressin is and what it is used for

The name of the medicine is Desmopressin 60, 120 and 240 micrograms sublingual lyophilisate contains the active substance desmopressin (as acetate). It belongs to a group of medicines called vasopressin and analogues (ATC code: H01BA02), which are agents with antidiuretic activity.

Desmopressin 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 take Desmopressin

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

General restrictions:

Do not take Desmopressin 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 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.

Take special care with Desmopressin:

- 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 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

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 antiinflammatory drugs (also known as NSAIDs) e.g. indometacin are taking a medicine containing loperamide for diarrhoea.

Desmopressin with food and drink

Taking Desmopressin at the same time as food may reduce its effect and duration of action.

- If you are taking this medicine for bedwetting or nocturia, you should limit your liquids intake from 1 hour before taking the tablet until 8 hours after taking the tablet.
If you drink too much it can lead to fluid build-up, diluting the salt in the body. This may occur with or without warnings or symptoms, which may include:
- unusual severe or prolonged headache
- nausea or vomiting
- unexplained weight gain
- in severe cases, seizures and unconsciousness.

If you get any of these symptoms, stop the treatment and see your doctor immediately.

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 or pharmacist for advice before taking this medicine.

Caution is advised if you are pregnant. 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, oedema (swelling due to the build up of fluid) and proteinuria (protein in the urine). Desmopressin can only be administered to pregnant women after careful benefit-risk assessment.

Driving and using machines

Desmopressin has no or negligible influence on your ability to drive and use machines.

Desmopressin contains sodium

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

3. How to take Desmopressin

Always take Desmopressin exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Desmopressin is intended for sublingual use (to be placed under the tongue where it will dissolve completely).

The recommended doses are:

Diabetes insipidus:

Your doctor will prescribe the dose most suitable for you.

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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 tablets 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.

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 recommended initial dose for children (from 5 years of age) and adults (up to 65 years of age) with normal urine concentrating ability, who have primary nocturnal enuresis, is 120 micrograms at bedtime. Depending on how well the bedwetting is controlled, your doctor may increase the dose to either two Desmopressin 120 micrograms sublingual tablets or one Desmopressin 240 micrograms sublingual tablet taken sublingually (under the tongue) at bedtime. The need for continued treatment is normally checked every three months.

Method of administration

Desmopressin is placed under the tongue where it dissolves without the need for water.

The tablet should be placed under the tongue and allowed to dissolve. **Do not swallow or chew or take with water.**

To remove the sublingual lyophilisate from the blister:

- lift the edge of the foil
- peel off the foil completely
- tip the sublingual lyophilisate out
- remove the sublingual lyophilisate from the blister.

Do not push sublingual lyophilisate through foil.

If you take more Desmopressin than you should

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

If you forget to take Desmopressin

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.

In the case of central diabetes insipidus, you must take the next dose as soon as you notice the mistake. Keep to the usual time interval until you take the next dose.

If you stop taking Desmopressin

Treatment should only be interrupted or stopped in consultation with your doctor.

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, 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 treatment immediately and contact your doctor if you experience any of the following

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 1,000 people:

- symptoms of anxiety
- nightmares
- mood swings
- sleepiness (sommolence)
- 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 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 Desmopressin

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 container or carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package, in order to protect from moisture.

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

6. Contents of the pack and other information

What Desmopressin contains

sublingual lyophilisate

Desmopressin 60 micrograms sublingual lyophilisate

Each sublingual lyophilisate contains 60 micrograms of desmopressin (as acetate).

Desmopressin 120 micrograms sublingual lyophilisate

Each sublingual lyophilisate contains 120 micrograms of desmopressin (as acetate).

Desmopressin 240 micrograms sublingual lyophilisate

Each sublingual lyophilisate contains 240 micrograms of desmopressin (as acetate).

The other ingredients are pullulan (E1204), mannitol (E421), trisodium citrate dihydrate (E 331), citric acid (E 330).

What Desmopressin looks like and contents of the pack

Desmopressin 60 micrograms sublingual lyophilisate white to off-white, round, lyophilized tablet, with a diameter of approximately 12 mm.

Desmopressin 120 micrograms sublingual lyophilisate white to off-white, round, lyophilized tablet, with a diameter of approximately 12 mm.

Desmopressin 240 micrograms sublingual lyophilisate white to off-white, round, lyophilized tablet, with a diameter of approximately 12 mm.

Blister packaging of 10 sublingual lyophilisates in packs of 30 or 90 or 100 sublingual lyophilisates.

The blister comprising PVC/polyamide/aluminium/polyamide/PVC blister with peel-off lidding of paper/PET/aluminium foil.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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