

PACKAGE LEAFLET: INFORMATION FOR THE USER

Desmopressin 60 micrograms Sublingual Tablets

Desmopressin 120 micrograms Sublingual Tablets

Desmopressin 240 micrograms Sublingual Tablets

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 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
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6. Contents of the pack and other information

1. WHAT DESMOPRESSIN SUBLINGUAL TABLETS ARE AND WHAT THEY ARE USED FOR

Desmopressin 60, 120 and 240 micrograms sublingual tablets contain desmopressin (as acetate). Each tablet contains 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). **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 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 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 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
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 restrictions.

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, oedema (swelling due to the build-up of fluid).

Driving and using machines

Desmopressin is unlikely to affect your ability to drive or operate machinery.

Desmopressin sublingual tablets contain:

- **aspartame (E 951):** this medicine contains 1.2mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- **sodium:** This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. HOW TO TAKE DESMOPRESSIN SUBLINGUAL TABLETS

Always take Desmopressin sublingual tablets 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.

Method of administration

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 container, do not take the broken pieces. Take a new tablet. The tablet will dissolve within 30 seconds and have a sweet taste due to the presence of the sweeteners mannitol and aspartame in the tablets. The tablets are supplied with desiccant canisters, which should not be put in the mouth.

Doses

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 720micrograms. 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 120micrograms 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 usual starting dose is one Desmopressin 120 micrograms sublingual tablets taken sublingually (under the tongue) 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.

If you take more Desmopressin sublingual tablets than you should

If you take more Desmopressin sublingual 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 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 taking 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 1,000 people:

- symptoms of anxiety
- nightmares
- mood swings
- sleepiness (somnia)
- 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 this medicine out of the sight and reach of children.

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

After opening the container, the tablets can be used for **1 month**.

Do not store above 25°C. Store in the original package to protect from moisture and light. The three desiccant canisters should not be removed from the bottle and keep the cap on the bottle as the tablets are sensitive to moisture.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Desmopressin sublingual tablets contain

- The active ingredient is desmopressin (as acetate). Each tablet contains 60, 120 or 240 micrograms of desmopressin (as acetate).
- The other ingredients are citric acid monohydrate, mannitol, crospovidone, aspartame (E 951), talc and sodium stearyl fumarate.

What Desmopressin sublingual tablets looks like and the contents of the pack

Desmopressin sublingual tablets are white to off white, circular, flat-faced tablets. Each tablet is engraved with D1, D2 or D3 on one side and plain on the other side indicating the strength of 60, 120 or 240 micrograms respectively. The tablet diameter is approximately 5.50 mm. Each pack contains 30, 40 or 100 tablets. Not all pack sizes will be marketed.

Marketing Authorisation Holder

Molecule Pharma Limited, 231 Kenton Road, Harrow, HA3 0HD, United Kingdom.

Manufacturer

Kinedexe UK Limited, Unit 15 Moorcroft, Harlington Road, Uxbridge, UB8 3HD, United Kingdom.

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