PACKAGE LEAFLET

Package leaflet: Information for the user

Desmopressin Newbury 60 micrograms sublingual tablets
Desmopressin Newbury 120 micrograms sublingual tablets
Desmopressin Newbury 240 micrograms sublingual tablets
desmopressin

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 [Product name] is and what it is used for

Desmopressin, the active substance in [Product name] acts like the natural hormone vasopressin and regulates the kidneys' ability to concentrate urine.

[Product name] is used to treat:
- Central diabetes insipidus (pituitary disorder leading to severe thirst and the emission of a large quantity of urine, usually pale and resembling water).
- Bed wetting in children from 5 years of age with normal ability to concentrate urine (involuntary nightly urination during sleep).
- Nocturia (a condition when a person wakes up frequently during the night to urinate) in adults below 65 years of age.

2. What you need to know before you take [Product name]

Do not take [Product name]:
- if you are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from polydipsia (abnormally high fluid intake), heart failure and other conditions that require treatment with diuretics
- if you have moderate or severely reduced kidney function
- if you have low sodium in your blood
- if you are unable to respect fluid restriction
- if you have disturbed hormone secretion (so-called SIADH)
- if you are over 65 years of age and suffer from nocturia (see section 1)
- if your child is under 5 years old and suffers from nocturnal enuresis (see section 1)

Warnings and precautions
Management of bedwetting (involuntary nightly urination) in children begins with lifestyle measures and night-time wetting alarm (a device that cause an sound or vibrating when becoming wet). If these measures fail or pharmacological therapy is needed, treatment with desmopressin may be initiated.

Talk to your doctor before using [Product name]:
- if you have coronary artery disease (blood vessels supplying the heart) or high blood pressure
- if you have a disease of the thyroid (gland in the throat) or the adrenal gland (gland above the kidney).
- if during the treatment you have a disease which causes fever, vomiting, diarrhoea.
- if during your treatment you feel headache, lack of appetite, nausea, vomiting, gain weight, confusion (difficulty understanding words, attention difficulties) or convulsions (violent and involuntary contractions of one or several limbs); these symptoms may be signs of a dangerous condition known as hyponatremia (low sodium in your blood)
    - for treatment of central diabetes insipidus: you should reduce water consumption and consult immediately a doctor. Your doctor will reduce the doses or interrupt the treatment during some hours.
    - for treatment of bedwetting or nocturia: you should stop the treatment, reduce the water consumption and immediately consult a doctor.
- if you are at risk of increased pressure in the skull

When treating bedwetting and nocturnal urination, liquids intake should be limited to the minimum possible in order to manage thirst during the period between 1 hour before to 8 hours after taking this medicine.
[Product name] should be used with caution in patients with disturbed fluid balance. Talk to your doctor if, in connection with an acute illness, you have a disturbed fluid and/or electrolyte balance.

Children
In children, the use of this medicine must be carried out under the supervision of an adult.
Do not give this medicine to children below 5 years of age.

Other medicines and [Product name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The effect of [Product name] can be increased, with a higher risk of an abnormal amount of fluid remaining in the body, if taken at the same time with certain medicines used to treat:
- depression (such as tricyclic antidepressants, selective serotonin reuptake inhibitors)
- psychosis (such as chlorpromazine)
- epilepsy (such as carbamazepine)
- diabetes (so-called sulphonylureas eg chloropropramide)
- diarrhea (such as loperamide)
- pain and inflammation (so-called NSAIDs)

The effect of [Product name] may be reduced if it is taken at the same time as certain medicines for:
- gas in the stomach (such as dimethicone)

[Product name] with food and drink
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.
The effect of this medicine may be decreased if the tablet is taken with a meal.

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.
There is limited experience in use of desmopressin during pregnancy.

[Product name] passes into breast milk, but is unlikely to affect breast-fed infants.

Driving and using machines
[Product name] has no or negligible effect on the ability to drive and use machines.

[Product name] contains 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.

[Product name] contains 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 [Product name]

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

The dose is established by your doctor, who will adjust it individually for you.
[Product name] should always be taken at the same time in relation to food intake.

The sublingual tablet must be placed under the tongue where it dissolves without water.

Diabetes insipidus
The usual dose for adults and children is 1-2 tablets under the tongue (60 micrograms tablet) 3 times daily.

Bedwetting
The usual dose is 1-2 tablets (120 micrograms tablet) under the tongue at night. You should take this medicine at bedtime. Liquids intake should be limited.

Your doctor will check every three months to see if the treatment should be continued. Your doctor may set a treatment-free period of at least one week.

Nocturia in adults
The usual dose is 1 tablet (60 micrograms tablet) under the tongue at bedtime.
Liquids intake should be limited.

Use in children
This medicine is used for treating diabetes insipidus and nocturnal bedwetting (see dosage for different treatment conditions above). Dosage is the same for children and adults only for diabetes insipidus.

If you take more [Product name] than you should
If you take more medicine than you should or if, for example, a child has accidentally ingested the medicine, contact a doctor, hospital or pharmacist immediately for risk assessment and advice.

Taking too much [Product Name] can prolong the effect of this medicine and increase the risk of fluid retention in the body and a low level of sodium in your blood. Symptoms of severe fluid retention include convulsions and unconsciousness.

If you forget to take [Product name]
Do not take double doses to make up for a forgotten tablet.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking [Product name]
If you have any further questions on the use of this medicine, ask your doctor pharmacist.

4. Possible side effects

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

If fluid intake is not limited according to the instructions above, abnormal amounts of fluid can accumulate in your body, which can lead to headaches, stomach pain, nausea/vomiting, weight gain, dizziness, confusion, malaise, spinning sensation and, in severe cases, convulsions and coma.
These signs can reflect more or less significant water retention. They usually appear with high doses of [Product Name] and disappear when the dose is reduced.

Adults
Very common (may affect more than 1 in 10 people):
- Headache

Common (may affect up to 1 in 10 people):
- Low sodium in the blood
- Dizziness
- High blood pressure
- Stomach pain
- Nausea
- Diarrhoea
- Constipation
- Vomiting
- Discomfort of bladder and urethra
- Swelling of hands, arms, feet or legs
- Fatigue

Uncommon (may affect up to 1 in 100 people)
- Sleeping difficulties
- Drowsiness
- Tingles
- Visual disturbances
- Overall spinning sensation (vertigo)
- Feeling your heartbeat
- Low blood pressure when standing up from a lying position
- Shortness of breath
- Stomach complaints (indigestion, flatulence, bloating)
- Sweating
- Itching
- Rash
- Hives
- Muscle spasms
- Muscle pain
- Chest pain
- Flu-like symptoms
- Weight gain
- Increase in liver enzymes
- Low potassium in the blood.

Rare (may affect up to 1 in 1,000 people)
- Confusion
- Allergic skin inflammation.

Frequency not known (frequency cannot be estimated from the available data)
- Anaphylactic reaction (severe allergic reaction)
- Dehydration
- High sodium in the blood

- Convulsions
- Weakness
- Coma.

Children
Common (may affect up to 1 in 10 people)
- Headache.

Uncommon (may affect up to 1 in 100 people)
- Rapidly changing emotions
- Aggression
- Nausea
- Stomach pain
- Vomiting
- Diarrhoea
- Discomfort in bladder and urethra
- Swollen hands and feet
- Fatigue.

Rare (may affect up to 1 in 1,000 people)
- Anxiety
- Nightmares
- Mood swings
- Drowsiness
- High blood pressure
- Irritability.

Frequency not known (frequency cannot be estimated from the available data)
- Anaphylactic reaction (severe allergic reaction)
- Low sodium in the blood
- Abnormal behaviour
- Emotional disturbances
- Depression
- Hallucinations
- Sleeping difficulties
- Reduced attention
- Increased muscle movements
- Cramps
- Nosebleeds
- Rash
- Allergic skin inflammation
- Sweating
- Hives.

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 national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Product name]

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 blister, label, carton or bottle after EXP. The expiry date refers to the last day of that month.

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

[For HDPE containers]
Store in the original package. Keep the bottle tightly closed in order to protect from moisture. Do no store above 30°C.

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 [Product name] contains

- The active substance is desmopressin
  [Product name] 60 micrograms sublingual tablets
  Each tablet contains 60 micrograms desmopressin (as desmopressin acetate)

  [Product name] 120 micrograms sublingual tablets
  Each tablet contains 120 micrograms desmopressin (as desmopressin acetate)

  [Product name] 240 micrograms sublingual tablets
  Each tablet contains 240 micrograms desmopressin (as desmopressin acetate)

- The other ingredients are: lactose monohydrate, maize starch, citric acid (E 330), croscarmellose sodium (E 468), magnesium stearate (E 470b)

What [Product name] looks like and contents of the pack

[Product Name] 60 micrograms sublingual tablet
White or almost white, round, biconvex tablet debossed with ‘I’ on one side and plain on other side, with 6.5 mm diameter and 2 mm thickness.

[Product Name] 120 micrograms sublingual tablet
White or almost white, octagonal, biconvex tablet debossed with ‘II’ on one side and plain on other side, with 6.5 mm length/ width and 2 mm thickness.

[Product Name] 240 micrograms sublingual tablet
White or almost white, square, biconvex tablet debossed with ‘III’ on one side and plain on other side, with 6 mm length/ width and 2 mm thickness.

[Product name] is supplied in carton box containing OPA/Al/PVC/PE-Al blisters with integrated desiccant layer in pack sizes of 10, 20, 30, 50, 60, 90, 100 sublingual tablets or unit dose perforated blisters of 10 x 1, 20 x 1, 30 x 1, 50 x 1, 60 x 1, 90 x 1 and 100 x1 sublingual tablets, or in HDPE bottles with PP caps with integrated desiccant containing 30 or 100 sublingual tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<[To be completed nationally]>

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

Manufacturer

<To be completed nationally>

<This medicine is authorised in the Member States of the European Economic Area under the following names:>

<{Name of the Member State}> <{Name of the medicine}>
<{Name of the Member State}> <{Name of the medicine}>

This leaflet was last revised in 2025-06-01