

## PACKAGE LEAFLET

### Package leaflet: Information for the user

**Desmopressine Hexal 60 microgram, tabletten voor sublinguaal gebruik**  
**Desmopressine Hexal 120 microgram, tabletten voor sublinguaal gebruik**  
**Desmopressine Hexal 240 microgram, tabletten voor sublinguaal gebruik**  
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 [nationally completed name] is and what it is used for
2. What you need to know before you use [nationally completed name]
3. How to take [nationally completed name]
4. Possible side effects
5. How to store [nationally completed name]
6. Contents of the pack and other information

### 1. What [nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance desmopressin which lowers the amount of urine that is produced by the kidneys.

[Nationally completed name] is used to treat:

- a chronic disease called **diabetes insipidus**, which causes extreme thirst and a constant production of large amounts of diluted urine. **Important:** this should not be confused with diabetes mellitus.
- **bedwetting** (involuntary nightly urination) in patients from 5 years old with normal ability to concentrate urine.

### 2. What you need to know before you take [nationally completed name]

**Do not take [nationally completed name] if you:**

- are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6).
- drink **unusually large amounts** of liquid
- have **heart problems or other diseases** for which you are treated with medicines to increase output through your kidneys
- have **moderate or severely reduced kidney function**
- know that you have **low sodium levels** in your blood

- have disturbed hormone secretion called **SIADH**.

### Warnings and precautions

Talk to your doctor before taking [nationally completed name]:

- regarding your fluid intake, **drink as little as possible** from **1 hour before** taking a tablet **up to 8 hours** after taking the tablet.
- if you are **elderly**.
- if you have a medical condition that causes **fluid and/or electrolyte imbalance in the body**, such as an infection, fever, or stomach inflammation.
- if you suffer from **severe bladder problems** or **reduced urine output**.
- if you suffer from **asthma, epilepsy, cystic fibrosis** or **migraine**.
- if you are a patient at risk of increased intracranial pressure (a condition you will be told about by your doctor).

### Other medicines and [nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of {[nationally completed name]} can be increased, with a higher risk of an abnormal amount of fluid remaining in the body, if you already take certain medicines:

- **medicines to treat depression called tricyclic or SSRI antidepressants**
- **carbamazepine** ( to treat epilepsy)
- **chlorpromazine** (to treat psychosis or schizophrenia)
- **medicines to treat diabetes called sulphonylureas**
- **loperamide** (to treat diarrhoea)
- **medicines to treat pain and/or inflammation**, the so-called non-steroidal anti-inflammatory drugs, such as indomethacin, ibuprofen

The effect of [nationally completed name] may be reduced if you already take certain medicines:

- **dimeticone** (to treat symptoms of gas in the stomach)

### [Nationally completed name] with food and drink

- Before you start taking this medicine, your doctor should advise you on how to take fluids, including alcoholic beverages.
- If you are taking this medicine for bedwetting, drink as little as possible from **1 hour** before taking a tablet until **8 hours** afterwards..
- 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

[Nationally completed name] can only be used during pregnancy as directed by a doctor. There is only limited experience using desmopressin acetate in pregnant women with diabetes insipidus.

[Nationally completed name] can be used during breastfeeding. [Nationally completed name] passes into breast milk but is unlikely to affect breast-fed babies.

If you are pregnant or breast-feeding, you think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

There is no evidence that desmopressin has a side effect on the ability to drive or use machines.

### **[Nationally completed name] contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

## **3. How to take [nationally completed name]**

Always take this medicine exactly as your doctor or pharmacist 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.

The recommended dose is:

- **Diabetes insipidus**  
**Adults and children** – 60 micrograms three times daily. Your doctor may increase the dose, depending on how well your symptoms are controlled.
- **Bedwetting (involuntary urination at night)**  
**Adults and children from 5 years old** – 120 micrograms at bedtime and after emptying the bladder. Your doctor may increase the dose to 240 micrograms at bedtime, depending on how well bedwetting is controlled. Checks are made every three months as to whether treatment should be continued by setting a treatment-free period of at least one week.

### **Use in elderly**

[Nationally completed name] should not be started until it has been established that the sodium in your blood is normal. This sodium level check must be repeated three days after the start of treatment if the dose is increased or if your doctor considers it necessary.

If you are taking this medicine for bedwetting, **drink as little as possible** from **1 hour** before taking a tablet **until 8 hours** afterwards.

### **Method of use**

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

### **If you take more [nationally completed name] than you should**

immediately contact your doctor, pharmacist or nearest hospital if this occurs.

Overdose may prolong the effect of desmopressin acetate and increase the risk of fluid retention in the body and a low level of sodium in your blood. Symptoms of severe fluid retention are including seizures and unconsciousness.

**If you forget to take [nationally completed name]**

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

**If you stop taking [nationally completed name]**

You should only change or stop your treatment if your doctor advises you to. 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.

**Stop treatment and see your doctor immediately if you have any of the following severe side effects:**

- multiple or severe symptoms of **fluid retention**. These are the side effects below that are marked with an asterisk (\*).
- **allergic reactions** such as skin rash, itching, fever, swelling of the mouth, tongue or airways leading to swallowing or breathing problems.

Side effects seen in 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
  - nausea\*
  - stomach pain\*
  - diarrhoea
  - constipation
  - vomiting\*
  - urination problems (frequent, abnormal urination during the day)
  - tissue swelling of hands, arms, feet or legs
  - fatigue
- **Uncommon** (may affect up to 1 in 100 people)
  - Sleeping difficulties
  - drowsiness
  - tingles
  - visual disturbances
  - vertigo\*
  - feeling of increased heartbeat
  - low blood pressure when standing up from a lying position
  - shortness of breath
  - stomach complaints (indigestion, heartburn, flatulence, bloating)
  - sweating
  - itching
  - skin rash

- hives
  - muscle spasms
  - muscle pain
  - urinary disorder (such as urgent urination)
  - feeling unwell\*
  - 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 reaction
  - **Frequency not known** (frequency cannot be estimated from the available data )
    - severe allergic reaction
    - seizures
    - dehydration
    - muscle weakness
    - coma
    - high sodium levels in the blood

Side effects seen in children up to 18 years:

- **Common** (may affect up to 1 in 10 people)
  - headache\*
- **Uncommon** (may affect up to 1 in 100 people)
  - emotional problems
  - aggression
  - stomach pain\*
  - nausea\*
  - vomiting\*
  - diarrhoea
  - tissue swelling of hands, arms, feet or legs
  - fatigue
- **Rare** (may affect up to 1 in 1,000 people)
  - anxiety
  - drowsiness
  - high blood pressure
  - irritability
  - nightmares
  - mood swings
- **Frequency not known** (frequency cannot be estimated from the available data )
  - severe allergic reaction
  - low sodium in the blood
  - abnormal behaviour
  - depression
  - hallucinations

- insomnia (hard to fall/stay asleep)
- reduced attention
- increased muscle movements
- seizure\*
- nosebleed
- allergic skin reaction
- rash
- 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 [nationally completed 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 carton 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 [nationally completed name] contains

The active substance is desmopressin.

*[Nationally completed name] <60 micrograms> <sublingual tablets>*

Each sublingual tablet contains 60 micrograms desmopressin (as desmopressin acetate).

*[Nationally completed name] <120 micrograms> <sublingual tablets>*

Each sublingual tablet contains 120 micrograms desmopressin (as desmopressin acetate).

*[Nationally completed name] <240 micrograms> <sublingual tablets>*

Each sublingual tablet contains 240 micrograms desmopressin (as desmopressin acetate).

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

#### What [nationally completed name] looks like and contents of the pack

### Sublingual tablets

*[Nationally completed name] <60 micrograms> <sublingual tablets>*

White or almost white, round, rounded on the upper and lower side, tablet debossed with 'I' on one side and plain on other side, with 6.5 mm of length and 2 mm of thickness..

*[Nationally completed name] <120 micrograms> <sublingual tablets>*

White or almost white, octagonal tablet, rounded on the upper and lower side, debossed with 'II' on one side and plain on other side, with 6.5 mm of length and 2 mm of thickness..

*[Nationally completed name] <240 micrograms> <sublingual tablets>*

White or almost white, square tablet, rounded on the upper and lower side, debossed with 'III' on one side and plain on other side, with 6.5 mm of length and 2 mm of thickness..

Aluminium/Aluminium blisters with integrated desiccant layer.

#### Pack sizes

30 sublingual tablets

### **Marketing Authorisation Holder and Manufacturer**

#### **Vergunninghouder:**

HEXAL AG  
Industriestrasse 25  
83607 Holzkirchen  
Duitsland

#### **Fabrikanten:**

Adalvo Limited  
Malta Life Sciences Park Building 1 Level 4  
Sir Temi Zammit Buildings  
San Gwann Industrial Estate  
SGN 3000 San Gwann  
Malta

Lek Pharmaceuticals d.d.  
Verovskova Ulica 57  
1526 Ljubljana  
Slovenië

Haupt Pharma Münster GmbH  
Schleebrueggenkamp 15  
Uppenberg  
48159 Münster  
Duitsland

#### **In het register ingeschreven onder:**

Desmopressine Hexal 60 microgram, tabletten voor sublinguaal gebruik – RVG 129995  
Desmopressine Hexal 120 microgram, tabletten voor sublinguaal gebruik – RVG 129996  
Desmopressine Hexal 240 microgram, tabletten voor sublinguaal gebruik – RVG 129997

**Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

Nederland	Desmopressine Hexal 60, 120, 240 microgram, tabletten voor sublinguaal gebruik
Spanje	Desmopresina Flas Sandoz 120 microgramos comprimidos sublinguales EFG
Italië	Desmopressina Sandoz

**Deze bijsluiter is voor het laatst goedgekeurd in juli 2023.**