PACKAGE LEAFLET

Package leaflet: Information for the user

Desmopressine 1A Pharma 60 microgram, tabletten voor sublinguaal gebruik
Desmopressine 1A Pharma 120 microgram, tabletten voor sublinguaal gebruik
Desmopressine 1A Pharma 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

[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 6 years old
- **frequent urination during the night** in adults

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 water output through your kidney **(diuretic treatment)**
- 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
Management of bedwetting (involuntary nightly urination) in children begins with lifestyle measures and night-time wetting alarm (the device that cause an acoustic 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 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 called organic vescico-sphincter abnormality.
- 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 coronary insufficiency, hypertension or are at a risk of intracranial hypertension.
- if you suffer from **severe bladder problems** or **reduced urine output.**
- if you suffer from **asthma, epilepsy, cystic fibrosis** or **migraine**.

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 takecertain 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**, 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.
- If you are taking this medicine for bedwetting or frequent urination during the night in adults (nocturia), 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 and

- in severe cases, seizures and unconsciousness.

If you get any of these symptoms, **stop the treatment and see your doctor immediately.**
If treatment is resumed, the water restriction should be stricter.

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 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**
  Adults and children from 6 years old – 120 micrograms at bedtime. 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.

- **Frequent urination during the night**
  Adults - 60 micrograms at bedtime. The dosage can be increased to 120 micrograms and then up to a maximum of 240 micrograms at 1 week intervals. Your urine output should be measured before you start treatment. If frequent urination during the night is not reduced after four weeks of treatment, consult your doctor, as the treatment should be stopped.

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

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.

Use in children
[Nationally completed name] is not recommended in children below 6 years old for treatment of bedwetting.

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 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, unconsciousness, a rapid increase in weight, heart beat, headache, nausea and vomiting.

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 (*).
- **hypersensitivity 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 heart beat
  - 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
  - seizuresdehydration
  - 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 content in the blood
  - abnormal behavior
  - depression
  - hallucinations
  - sleeping difficulties (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.

[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.
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 tablet, rounded on the upper and lower side, 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.
Plastic containers with polypropylene caps with integrated desiccant.

Pack sizes
Aluminium/aluminium blisters: 30 and 100 sublingual tablets
Plastic containers: 30 and 100 sublingual tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Vergunninghouder:
1A Pharma GmbH

Industriestrasse 18
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 Muenster
Duitsland

In het register ingeschreven onder:
Desmopressine 1A Pharma 60 microgram, tabletten voor sublinguaal gebruik – RVG 129992
Desmopressine 1A Pharma 120 microgram, tabletten voor sublinguaal gebruik – RVG 129993
Desmopressine 1A Pharma 240 microgram, tabletten voor sublinguaal gebruik – RVG 129994

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

Nederland	Desmopressine 1A Pharma 60, 120, 240 microgram, tabletten voor sublinguaal gebruik
Frankrijk	DESMOPRESSINE SANDOZ 60, 120, 240 microgrammes, comprimé sublingual
Zweden	Desmopressin Sandoz

Deze bijsluiter is voor het laatst goedgekeurd in juli 2023.