

Package leaflet: information for the user

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.

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 build up 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 your medicine is Desmopressin 120 and 240 micrograms sublingual tablets (called Desmopressin throughout this leaflet). They are oral lyophilisates, they look like tablets but are much softer and lighter. Intended for sublingual use (to be placed under the tongue where it will dissolve completely).

Desmopressin is available in two strengths: 120 and 240 micrograms. It contains Desmopressin acetate, an antidiuretic (reduces urine production)..

Desmopressin is used to treat:

- diabetes insipidus (a condition that causes 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).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DESMOPRESSIN

Do not take Desmopressin if you:

- have a serious heart or kidney disease
- are taking diuretics (water tablets)
- are allergic to any of the ingredients listed in section 6 of this leaflet

- drink unusually large quantities of fluids, including alcohol

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.

Warnings and precautions

Please consult your doctor before taking Desmopressin if you:

- have an illness causing fluid and/or salt imbalance e.g. vomiting, diarrhoea, systemic infections, fever or gastroenteritis
- have a medical condition that could be made worse by fluid and/or electrolyte disturbance. Condition where your blood sodium levels are too low or you are likely to build up too much water in your body.

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 or epilepsy
- 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

Pregnancy and breast-feeding

If you are pregnant or planning a pregnancy, please inform your doctor before you take Desmopressin, as 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).

If you are breast-feeding ask your doctor or pharmacist for advice before taking Desmopressin.

Desmopressin 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.

Desmopressin 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 DESMOPRESSIN

It is important to use this medicine as directed by your doctor. Desmopressin is intended for sublingual use (to be placed under the tongue where it will dissolve completely).

Do NOT take more than the prescribed dose in any 24 hour period.

If you have the impression that the effect of Desmopressin is too strong or too weak, talk to your doctor or pharmacist.

The usual doses are:

Treatment of diabetes insipidus:

Your doctor will prescribe the dose most suitable for you. The most common doses in adults and children are either one Desmopressin 60 micrograms or one Desmopressin 120 micrograms three times a day.

Treatment of extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland:

Your doctor will prescribe the most suitable dose for you based on the concentration of your urine.

If you take more of this medicine than you should

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

If you forget to take this medicine

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

If you are a patient with diabetes insipidus, please consult your doctor or pharmacist immediately.

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 USING Desmopressin if you experience:

- unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting
- itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing (signs of allergic reactions).

If you experience any of the above side effects, you should contact your doctor or go to the nearest casualty department immediately.

Most people using Desmopressin find it causes them no problems. However, common side effects can include:

- headache
- stomach pain

Very rare cases of emotional disorders including aggression in children have also been reported.

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

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.



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mm 5'1

Blister

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

HDPE bottles

Store in the original package. Keep the bottle tightly closed 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 Desmopressin contains

- The active substance is desmopressin.
 - Desmopressin 120 micrograms sublingual tablets
Each tablet contains 120 micrograms desmopressin (as acetate)
 - Desmopressin 240 micrograms sublingual tablets
Each tablet contains 240 micrograms desmopressin (as acetate)
- The other ingredients are: lactose monohydrate, maize starch, citric acid croscarmellose sodium magnesium stearate

What Desmopressin looks like and contents of the pack

Desmopressin 120 micrograms sublingual tablets
White or almost white, octagonal, biconvex tablet debossed with 'II' on one side and plain on other side, with 6.5 mm diameter and 2 mm thickness.

Desmopressin 240 micrograms sublingual tablets
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.

Desmopressin is supplied in a carton box containing OPA/Al/PVC/PE-Al blisters with integrated desiccant layer with 10 tablets each, in pack sizes of 10, 30, 60, 90 and 100 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 and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited
12 New Fetter Lane,
London,
EC4A 1JP,
United Kingdom

Manufacturer(s)

Haupt Pharma Münster GmbH
Schleebrüggenkamp 15,
D-48159 Münster,
Germany

or

Adalvo Ltd.,
Malta Life Sciences Park,
Building 1, Level 4, Sir Temi Zammit Buildings,
San Gwann, SGN 3000 Malta

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ZENTIVA

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min. 6 mm Freiraum für Flattermarken / free space for marks on side

min. 6 mm Freiraum für Flattermarken / free space for marks on side

1,5 mm

8,5-10,5 mm



10-12 mm Freiraum für Pharmacode-System
10-12 mm free space for Pharmacode system