

Product Name	Demovo 360 micrograms/ml Oral Solution
MA Number	PL 44490/0008
Component	Patient Leaflet (oral solution)
Artwork Number	PL-DES-OS-360-REV 02

Package leaflet: Information for the patient

DEMOVO® 360 micrograms/ml Oral Solution 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 Demovo is and what it is used for
2. What you need to know before you take Demovo
3. How to take Demovo
4. Possible side effects
5. How to store Demovo
6. Contents of the pack and other information

1. What Demovo is and what it is used for

The ingredient that makes Demovo work (the active substance) is called desmopressin. Desmopressin is very similar to a substance that is produced naturally in the body (the pituitary hormone vasopressin), which temporarily reduces the amount of urine produced by the body. This medicine is intended for oral use only.

This medicine is used to treat:

- Central diabetes insipidus, a disease characterised by causing extreme thirst and continuous production of large volumes of dilute urine as a result of insufficient production of the hormone vasopressin.
- Bed-wetting (involuntary nightly urination or primary nocturnal enuresis) in patients older than 5 years with normal capacity to concentrate urine.

2. What you need to know before you take Demovo

Do not take Demovo:

- if you are **allergic** (hypersensitive) to **desmopressin** or any of the **other ingredients** of this medicine (listed in section 6)
- if you **drink** unusually **large amounts** of fluid (have habitual or psychogenic polydipsia)
- if you take **medicines which increase urine production** (diuretics)
- if you suffer from **heart problems**
- if you suffer predisposition to or have **low levels of sodium** in your blood (hyponatremia)
- if you suffer from reduced **kidney** function
- if you have **uncontrolled blood pressure**
- if you suffer from the 'Syndrome of Inappropriate High Secretion of Antidiuretic Hormone' (**SIADH**)

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

When taking this medicine, avoid excessive fluid intake because it may lead to a build-up of water in the body and / or decrease in blood sodium with or without side effects (see section 4 – Possible side effects).

Special care with this medicine is required to avoid build-up of water in the body and decreased blood sodium:

- if you are elderly
- if you have a medical condition causing **fluid and / or electrolyte imbalance** in the body, such as an infection, fever or stomach upset
- if you suffer from a **serious bladder problem or impaired urine outflow**
- if you suffer from **asthma, epilepsy and migraine**
- if you have **reduced renal function and / or cardiovascular disease**. In chronic renal disease, the antidiuretic effect of desmopressin would be less than usual.

Other medicines and Demovo

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

- **Tricyclic or SSRI antidepressants** (used to treat depression)
- **Carbamazepine** (used to treat epilepsy)
- **Chlorpromazine** (used to treat psychosis or schizophrenia)
- **Medicines for pain and / or inflammation** called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. indomethacin, ibuprofen, acetylsalicylic acid
- **Loperamide** (used to treat diarrhoea)
- **Diuretic agents**

These medicinal products increase the risk of build-up of water, which dilutes the salt in the body.

- Dimeticone (used in the treatment of wind), due to decreased absorption of desmopressin.

Demovo with food and drink

At low doses, this medicine may be affected by food intake. If you notice that this medicine is less effective, then you should take it without food before increasing the dose.

When using this medicine for bed-wetting keep your **fluid intake to a minimum** from **1 hour before** you take the Demovo dose **until 8 hours after** a dose.

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.

It is preferable to avoid using this medicine during pregnancy.

Desmopressin passes into breast milk. If you are going to be treated with desmopressin, you should stop breast-feeding.

Driving and using machines

Demovo does not affect your ability to drive and use machines.

Demovo contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

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

3. How to take Demovo

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

Usual doses

Treatment of central diabetes insipidus:

Adults and Children: Your doctor will prescribe the dose most suitable for you. The usual **starting dose** is 0.25 ml (90 micrograms) three times daily. Subsequently, the doctor will adjust the dose according to individual patient response. The **usual daily dose** is between 0.5 ml (180 micrograms) to 3 ml (1080 micrograms) of this medicine. The **maintenance dose** ranges from 0.25 to 0.5 ml (90 – 180 micrograms) of this medicine three times per day.

It is important to note if symptoms of build-up of water in the body and / or decreased blood sodium appear (see section 4 – Possible side effects). If so, treatment will be stopped and the dose will be changed.

Bed-wetting (involuntary nightly urination or primary nocturnal enuresis) in patients older than 5 years:

Adults and Children: The usual starting dose is 0.5 ml (180 micrograms) of this medicine one hour before bedtime. The dose may be increased up to 1 ml (360 micrograms) of this medicine if the starting dose is not enough. The need for continued treatment is normally checked every three months by introducing a treatment free period of at least one week.

Elderly: If the doctor decides to treat you, your blood sodium levels should be measured before and three days after starting the treatment and if the dose is increased or at any time your doctor finds it necessary.

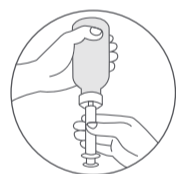
Monitoring your fluid intake is important. If symptoms of build-up of water in the body and / or decreased blood sodium occur (see section 4 – Possible side effects), discontinue treatment. Once treatment is restored, fluid intake will be rigorously controlled.

Instructions for use:

1. Open the bottle (on first opening the seal is broken).

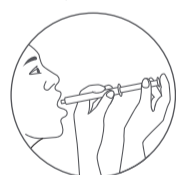


2. Insert the oral syringe into the pourer and turn the bottle upside down to fill it with the dose to be administered.



3. Take the oral syringe out of the bottle and check to see that the correct amount appears in the bottom of the syringe.

4. Hold the syringe to your mouth and release the dose into your mouth.



5. Rinse with water after each use and close the bottle. Keep the bottle in the outer carton to protect from light.

If you take more Demovo than you should

An overdose may lengthen the effect of desmopressin and increase the risk of water build up in the body and / or low levels of sodium in your blood. Symptoms may include headache, nausea and vomiting, weight gain and in severe cases convulsions. It is recommended to stop the treatment, restrict fluid intake and start symptomatic treatment if necessary.

If you take more Demovo than prescribed, contact your doctor or pharmacist immediately.

If you forget to take Demovo

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

If you stop taking Demovo

Do not stop taking Demovo before completing the treatment as it may not have the expected effect. You should only change or stop your treatment if advised by your doctor.

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 taking Demovo and see a doctor or go to a hospital straight away if the following occur:

- **Common** (occurs in less than 1 in 10 users): symptoms of a **build-up of water** in the body such as unusually bad or prolonged headache, feeling or being sick, unexplained weight gain and in serious cases, fits or unconsciousness.
- **Very rare** (occurs in less than 1 in 10,000 users): **allergic reactions** such as rash, itching, fever, swelling of your lips, face, throat or tongue causing difficulties in swallowing or breathing.

Tell your doctor or pharmacist if you notice any of the following other side effects:

- **Very common** (occurs in more than 1 in 10 users): headache.
- **Common** (occurs in less than 1 in 10 users): abdominal pain, nausea.
- **Very rare** (occurs in less than 1 in 10,000 users): emotional disturbances in children, allergic reactions.

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. Website: 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 Demovo

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Store in the original package.

After first opening, the product should be stored below 25°C for up to 4 weeks.

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

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 Demovo contains

The active substance is desmopressin. Each ml of the oral solution contains 360 micrograms of desmopressin (as acetate).

The other ingredients are sodium methylparahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217), hydrochloric acid (for pH adjustment) and purified water.

What Demovo looks like and contents of the pack

Demovo is a clear solution filled into an amber glass bottle and capped with a low density polyethylene (LDPE) pourer, provided with a high density polyethylene (HDPE) screw cap. The bottle contains 15 ml of solution. A graduated 1.5 ml dosing syringe is supplied in each pack. The syringe is graduated from 0 to 1.5 ml, with divisions of 0.1 ml. The graduation corresponding to the doses of 0.25 ml, 0.5 ml and 1.0 ml are specifically marked.

Demovo is available in packs (one carton containing a bottle with 15 ml of solution and one administration device) and in multipacks comprising 3 individual packs, each containing 15 ml of solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Other sources of information

Detailed information on this medicine is available on the website of the Medicines and Healthcare Products Regulatory Agency (MHRA).