

DDAVP®/ Desmopressin

100 micrograms/ml Nasal Drops, Solution

Desmopressin acetate



Read all of this leaflet carefully before you start using 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 DDAVP/Desmopressin Nasal Drops, Solution is and what it is used for
2. What you need to know before you use DDAVP/Desmopressin Nasal Drops, Solution
3. How to use DDAVP/Desmopressin Nasal Drops, Solution
4. Possible side effects
5. How to store DDAVP/Desmopressin Nasal Drops, Solution
6. Contents of the pack and other information

1. What DDAVP/Desmopressin Nasal Drops, Solution is and what it is used for

DDAVP/Desmopressin Nasal Drops, Solution is for nasal use only. It contains desmopressin acetate, an antidiuretic (reduces urine production).

It is used:

- to diagnose and treat cranial diabetes insipidus (a condition which causes extreme thirst and the continuous production of large volumes of dilute urine). *IMPORTANT: This should not be confused with diabetes mellitus (sugar diabetes)*
- as a test to check if the kidneys are functioning properly (renal function test)

2. What you need to know before you use DDAVP/Desmopressin Nasal Drops, Solution

Do not use DDAVP/Desmopressin Nasal Drops, Solution:

- if you are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- if you have a serious heart or kidney disease
- if you are taking diuretics (water tablets)
- if you drink unusually large quantities of fluids, including alcohol
- if you have known hyponatraemia (serum sodium levels below normal range)
- If you have syndrome of inappropriate secretion of anti-diuretic hormone, a hormone regulating urine production (SIADH)

Warnings and precautions

Talk to your doctor or pharmacist before using DDAVP/Desmopressin Nasal Drops, Solution.

Please consult your doctor before you use DDAVP/Desmopressin Nasal Drops, Solution:

- if you have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, infections, fever or gastroenteritis
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance (conditions where your blood sodium levels are too low or you are likely to build up too much water in your body, e.g. hyponatraemia)
- if you suffer from heart disease or reduced kidney function
- if you have cystic fibrosis
- if you have difficulty or problems passing urine
- if you suffer from bladder problems e.g. incontinence (inability to hold in urine), hesitance in starting urination, frequent urination and/or urgent urination
- if you have been warned that you are at risk of increased intracranial pressure
- if you have high blood pressure

Use with caution in very young and older patients.

Renal function testing in children below 1 year old should only be performed under carefully supervised conditions in hospital.

If any of these apply to you, or if you are not sure, contact your doctor before taking DDAVP/Desmopressin Nasal Drops, Solution.

Other medicines and DDAVP/Desmopressin Nasal Drops, Solution

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Please inform your doctor or pharmacist:

- if you are on medication for depression, epilepsy or type II diabetes
- you are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin or ibuprofen

DDAVP/Desmopressin Nasal Drops, Solution with food and drink

- You should avoid drinking large amounts of fluid while you are being treated with DDAVP/Desmopressin Nasal Drops, Solution 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. When used for diagnostic purposes (renal function test): limit fluid intake to no more than 500 ml from 1 hour before until 8 hours after the dose.
- Avoid swallowing water when swimming to prevent a build-up of water in the body.

Pregnancy, breastfeeding 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.

3. How to use DDAVP/Desmopressin Nasal Drop, Solution

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

The usual doses are:

Diagnosis of diabetes insipidus (adults and children):

Your doctor will prescribe a dose of 0.2 ml (20 micrograms).

Treatment of diabetes insipidus:

Your doctor will prescribe the dose most suitable for you.

The most commonly used doses are:

Adults: 0.1 ml to 0.2 ml once or twice daily (10 to 20 micrograms once or twice daily).

Children: 0.05 ml to 0.1 ml once or twice daily (5 to 10 micrograms once or twice daily). A lower dose may be required for infants.

Renal function test:

To check if the kidneys are functioning properly, your doctor will prescribe the following single dose:

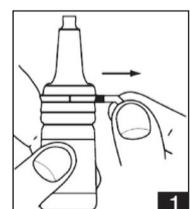
Adults: 0.4 ml (40 micrograms)

Children (> 1 year): 0.2 ml (20 micrograms)

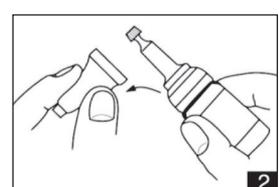
Infants (< 1 year): 0.1 ml (10 micrograms)

PATIENT INSTRUCTIONS

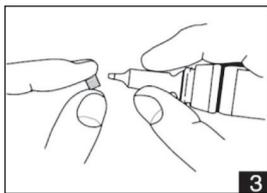
1. Pull plastic tag on neck of bottle.



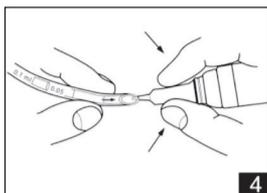
2. Break security seal and remove plastic cap.



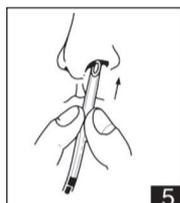
3. Twist off the small seal from the dropper. You can use the same seal reversed to prevent any subsequent leaks.



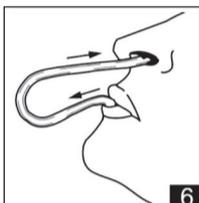
4. One end of the tube is marked with measurements - take this end of the tube in one hand. With your other hand, place your fingers around the dropper of the bottle (see diagram below). Insert the top of the dropper in a downward position into the end of the tube marked with an arrow and squeeze the dropper until the solution has reached your desired measurement. The tube has 5 dosing marks: 0.025 ml, 0.050 ml, 0.100 ml, 0.150 ml and 0.200 ml. If you have difficulty filling the tube, you can use a syringe to help with filling the tube.



5. Hold the tube with your fingers approximately 3/4 inch from the end and insert it into the nostril until the tips of the fingers reach the nostril (see diagram).



6. Put the other end of the tube into your mouth. Hold your breath, tilt back your head and then blow with a short strong puff through the tube so that the solution reaches into your nose.



7. If this product is for a child the dose should be given or supervised by an adult.

8. After use, place the seal on the dropper and close the bottle with the plastic cap. Wash the tube in water and shake thoroughly, until no more water is left. The tube can then be used for the next application.



If you use more DDAVP/Desmopressin Nasal Drops, Solution than you should:

If you have used more DDAVP/Desmopressin Nasal Drops, Solution than you should, talk to your doctor or pharmacist immediately.

If you forget to use DDAVP/Desmopressin Nasal Drops, Solution:

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

If you are a patient with diabetes insipidus, please consult your doctor or pharmacist for advice

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 USING DDAVP/Desmopressin Nasal Drops, Solution if you experience:

- allergic reactions including itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing
- unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting (signs and symptoms of water retention which can occur if too much fluid is consumed)

Low levels of sodium in your blood can lead to fits. This is more likely to happen if you drink large amounts of fluid while receiving this medication.

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

Other side effects associated with DDAVP/ Desmopressin Nasal Drops, Solution are listed below, starting with the most common.

- Very common:** may affect more than 1 in 10 people
- blocked or runny nose
 - *reported primarily in children and adolescents:* body temperature increased
- Common:** may affect up to 1 in 10 people
- trouble sleeping (insomnia)
 - nose bleeds
 - gastroenteritis
 - abdominal pain (primarily in connection with hyponatraemia)
 - *reported primarily in children and adolescents:* emotional instability, nightmare, nervousness, aggression, upper respiratory tract infection

Not known:

- frequency cannot be estimated from the available data
- dehydration
 - convulsions, coma
 - dizziness
 - sleepiness
 - high blood pressure
 - shortness of breath (dyspnoea)
 - diarrhoea
 - hives
 - muscle spasms
 - fatigue
 - swelling due to a build-up of fluid
 - chest pain
 - chills

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DDAVP/ Desmopressin Nasal Drops, Solution

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 and label after EXP. The expiry date refers to the last day of that month.

DDAVP/Desmopressin Nasal Drops, Solution should be stored at 2°C - 8°C (in a refrigerator). Keep the container in the outer carton. Do not freeze.

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 DDAVP/Desmopressin Nasal Drops, Solution contains.

The active substance is desmopressin acetate. Each 1 ml of the solution contains 100 micrograms of the active ingredient, desmopressin acetate.

The other ingredients are chlorobutanol hemihydrate (preservative), sodium chloride, hydrochloric acid and purified water.

What DDAVP/Desmopressin Nasal Drops, Solution looks like and contents of the pack

DDAVP/Desmopressin Nasal Drops, Solution is supplied in a brown glass bottle with a plastic cap. A plastic tube is provided with each pack to enable you to administer your prescribed dose. The tube has 5 dosing marks: 0.025 ml, 0.050 ml, 0.100 ml, 0.150 ml and 0.200 ml. Each bottle contains 2.5 ml of solution.

Marketing Authorisation Holder

Ferring Ireland Ltd., United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24

Manufacturer

Ferring GmbH, Wittland 11, D-24109 Kiel, Germany.

This leaflet was last revised in 09/2015.

DDAVP, FERRING and the FERRING logo are trademarks of Ferring B.V. © 2015 Ferring B.V.

Date: 24 Aug 2015

Title	Leaflet DDAVP DESMOPRESSIN nasal drops sol 0.1mg/ml vial 1x 2.5ml IE		
Item N°	2009054009	Perigord N°	260949
Item version	E-2009054009.01	Barcode N°	2436
Proof N°	03	E-MS N°	3001D
Country	IE	Size (mm)	180 x 420
Colours	Pro Black		
FERRING PHARMACEUTICALS			
Name			
Date			
Signature			
Variable Data	Translation		
line 1:			
line 2:			
line 3:			