DDAVP®/Desmopressin Intranasal Solution

desmopressin acetate

PATIENT INFORMATION

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet, you may need to use it again
- If you have further questions, please ask your doctor or pharmacist
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Your medicine is called DDAVP/Desmopressin Intranasal Solution. It is a clear, colourless solution for nasal use only.
- each 1ml of the solution contains 100 micrograms of the active ingredient, desmopressin acetate
- other ingredients in this medicine are chlorobutanol (preservative), sodium chloride to adjust the concentration, a small amount of hydrochloric acid to adjust the acidity of the solution and purified water
- it is presented in a brown glass vial covered with a plastic cap. A calibrated plastic tube (rhinyle) is provided with each pack to enable you to administer your prescribed dose. Each vial contains 2.5ml of solution.

Marketing Authorisation Holder: Ferring Pharmaceuticals Ltd., The Courtyard, Waterside Drive, Langley, Berkshire SL3 6EZ (UK).

Manufacturer: Ferring AB, Soldatorpsvägen 5, SE-200 61 Limhamn, Sweden.

1. What DDAVP/Desmopressin Intranasal Solution is and what it is used for

This medicine 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)
- to treat patients with multiple sclerosis suffering from nocturia (the need to get up at night to pass urine)
- as a test to check if the kidneys are functioning properly (renal function test).

2. Before you use DDAVP/Desmopressin Intranasal Solution

There are general restrictions, precautions and warnings which apply to all patients using this medicine and there are additional restrictions, precautions and warnings which apply depending on the use of this medicine.

General restrictions (all patients):
Do not use this medicine:
- 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 are allergic to any of the ingredients listed.

General precautions and warnings (all patients):
All patients on treatment with this medicine should avoid excessive fluid intake as this may lead to a build up of water in the body.

Please consult your doctor before using this medicine:
- if you are on medication for depression or epilepsy
- if you are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indometacin
- if you have cystic fibrosis
- if you have a medical condition causing fluid and/or electrolyte imbalance
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance.

Additional restrictions, precautions and warnings:
In addition to the general restrictions, precautions and warnings:

If you are a patient with nocturia caused by multiple sclerosis:
Do not use this medicine:
- if you are over 65 years old
- if you are taking medication for high blood pressure or have been told that your blood pressure is abnormal.

When using this medicine:
- fluid intake must be limited to a minimum from 1 hour before until 8 hours after a dose.

If you are using this medicine for the diagnosis of diabetes insipidus or for the renal function test:
- fluid intake must be limited and not exceed 500ml from 1 hour before until 8 hours after the dose.

Pregnancy:
If you are pregnant or planning a pregnancy, please inform your doctor before you use this medicine as blood pressure monitoring is recommended due to the increased risk of pre-eclampsia. Symptoms of pre-eclampsia include high blood pressure, oedema (swelling due to the build up of fluid) and proteinuria (protein in the urine).

Breast-feeding:
If you are breast-feeding ask your doctor or pharmacist for advice before using this medicine.

Taking/using other medicines:
Please inform your doctor or pharmacist if you are taking or have recently taken or used any other medicines - even those not prescribed.

3. How to use DDAVP/Desmopressin Intranasal Solution

See reverse side for instructions on use of the product. It is important that you do NOT use more than the prescribed dose in any 24 hour period. If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

Diagnosis of diabetes insipidus (adults and children):
Your doctor will prescribe a dose of 20 micrograms (0.2ml).

Treatment of diabetes insipidus:
Your doctor will prescribe the dose most suitable for you. The most commonly used doses are:
Adults (including the elderly):
10 to 20 micrograms (0.1ml to 0.2ml) once or twice daily.
Children:
5 to 20 micrograms (0.05ml to 0.2ml) daily. A lower dose may be required for infants.

Nocturia caused by multiple sclerosis:
Your doctor will prescribe a dose of 10 to 20 micrograms (0.1ml to 0.2ml) at bedtime. The prescribed dose should NOT be used more than once in any 24 hour period. Your doctor will check your blood pressure and weight at regular intervals.

Renal function test:
To check if the kidneys are functioning properly, your doctor will prescribe the following single dose:
Adults: 40 micrograms (0.4ml)
Children: (1-15 years): 20 micrograms (0.2ml)
Infants: (to 1 year): 10 micrograms (0.1ml)

continued overleaf
If you use more of this medicine than you should:
If you have used more of this medicine than you should, talk to your doctor or pharmacist immediately.

If you forget to use this medicine:
Do not use double doses to make up for forgotten doses. If you are a patient with nocturia caused by multiple sclerosis, do not use this medicine until the usual time for your next dose. If you are a patient with diabetes insipidus, please consult your doctor or pharmacist for advice.

4. Possible side effects
Most people using this medicine find it causes them no problems. However, like all medicines, this medicine can have side effects.

Excessive fluid intake may lead to a build up of water which dilutes the salt in the body in severe cases. This can become a serious problem and may lead to convulsions. Early symptoms may include an unusually bad or prolonged headache, confusion, unexplained weight gain, nausea or vomiting. If you experience one or more of these symptoms, stop using this medicine. Tell your doctor immediately or go to your nearest casualty department.

Side effects include headache, stomach pain, nausea, blocked or runny nose or nose bleeds. Isolated cases of allergic skin reactions and more severe general allergic reactions have been reported. Very rare cases of emotional disorders including aggression in children have been reported.

If you experience one or more of these side effects or any other undesirable effects, please tell a pharmacist, nurse or doctor.

5. Storing DDAVP/Desmopressin Intranasal Solution
Keep this medicine out of the reach and sight of children. This medicine should be stored at 2°C - 8°C (in a refrigerator). Keep vial in the outer carton. Do not use this medicine past the expiry date on the packaging.

If you are unsure about the storage, ask your pharmacist.

DDAVP/Desmopressin Intranasal Solution:
PL 03194/0001R
This leaflet was revised in May 2008.

DDAVP is a registered trademark.

PATIENT INSTRUCTIONS
It is important to use this medicine as directed by your doctor. The pharmacy label on the vial should tell you when to use this medicine and how much to use. If it does not, or you are not sure, ask your doctor or pharmacist.

How to use DDAVP/Desmopressin Intranasal Solution:

1. Pull plastic tag on neck of vial.
2. Break security seal and remove plastic cap.
3. Twist small knurled seal from the dropper. Use the same seal reversed to prevent subsequent leakage, especially if the vial is not stored upright.
4. Take the calibrated part of the plastic tube (rhinyle) in one hand and place the fingers of the other hand around the cylindrical part of the dropper. Insert the top of the dropper in a downward position into the end of the rhinyle marked with an arrow and squeeze the dropper until the solution has reached the desired mark. The un-numbered mark between the end and the 0.05ml mark is approximately at the 0.025ml position. If difficulty is experienced in filling the rhinyle, a diabetic or tuberculin syringe may be used to draw up the dose and load the rhinyle.
5. Hold the rhinyle with the fingers approximately 1/4 inch from the end and insert it into the nostril until the tips of the fingers reach the nostril.
6. Put the other end of the rhinyle into the mouth. Hold the breath, tilt back the head and then blow with a short strong puff through the rhinyle so that the solution reaches the right place in the nasal cavity. Through this procedure, medication is limited to the nasal cavity and the preparation does not pass down into the back of the throat.
7. After use, close the vial with the plastic cap, wash the rhinyle in water and shake thoroughly, until no more water is left. The rhinyle can then be used for the next application.