Package Leaflet: Information for the User

DDAVP®/Desmopressin 4 micrograms/ml Solution for Injection

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What DDAVP/Desmopressin Injection is and what it is used for
2. Before DDAVP/Desmopressin Injection is given
3. How DDAVP/Desmopressin Injection will be given
4. Possible side effects
5. How to store DDAVP/Desmopressin Injection
6. Contents of the pack and other information

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

DDAVP/Desmopressin Injection is a clear, colourless solution. It contains desmopressin acetate, an antidiuretic (reduces urine production).

It is used:

- to diagnosis 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).*

- during surgery or following trauma in patients with mild to moderate haemophilia (blood condition) or von Willebrand's disease (blood clotting condition) to increase blood clotting factors *(Note: DDAVP/Desmopressin Injection is not suitable for every patient or for the treatment of all types of haemophilia or von Willebrand's disease).*

- as a test to check if the kidneys are functioning properly (renal concentration capacity test).

2. Before DDAVP/Desmopressin Injection is given

DDAVP/Desmopressin Injection will not be given if you:

- are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- suffer from angina
- have known or suspected cardiac insufficiency (heart failure in which the heart is not able to pump enough blood throughout the body)
- have any other condition requiring treatment with diuretics (water tablets)
- suffer from polydipsia (excessive thirst and increased fluid intake) or psychogenic polydipsia (psychologically caused increased thirst and increased fluid intake)
- if you have or have had hyponatraemia (low sodium level in your blood)
- have syndrome of inappropriate secretion of anti-diuretic hormone, SIADH (hormone secretion disorder)
- suffer from von Willebrand's disease Type IIb

DDAVP/Desmopressin Injection will not be given for a renal function test if you:

- have high blood pressure or heart disease

Warnings and Precautions

Talk to your doctor before DDAVP/Desmopressin Injection is given to you.

Please consult your doctor, pharmacist or nurse before DDAVP/Desmopressin Injection is given if you:

- have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, infections or fever
- 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 have low levels of sodium in your blood
- suffer from moderate or severe kidney disease
- have a history of blood clotting or heart disease
- have cystic fibrosis
- if you suffer from severe bladder dysfunction and problems urinating
- if you have been warned that you are at risk of increased intracranial 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.

Treatment without simultaneous reduction of fluid intake may lead to water retention and/or mineral imbalances with or without accompanying warning signs and symptoms such as headache, nausea/vomiting, weight gain and, in severe cases, convulsions.

Other medicines and DDAVP/Desmopressin Injection

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

Please inform your doctor or pharmacist if you are taking:

- other medicines that could affect water and/or sodium levels in your body.
- tricyclic antidepressants or selective serotonin reuptake inhibitors (e.g. to treat depression), chlorpromazine (e.g. to treat psychosis or schizophrenia), carbamazepine (e.g. to treat epilepsy) or antidiabetic medicinal products from the sulfonylurea group (to treat type II diabetes)
- a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin or ibuprofen
- opioids

These medicines may increase the risk of water retention in your body.

DDAVP/Desmopressin Injection with food and drink

- Your doctor will advise you about the intake of fluids.
- You should avoid drinking large amounts of fluid while you are being treated with DDAVP/Desmopressin Injection as this could lead to build up of water which dilutes the salt in the body. This is a serious problem and may lead to convulsions.
- When used to control bleeding in haemophilia or von Willebrand's disease, you should only drink enough fluid to satisfy your thirst.
- When used for diagnostic purposes (kidney function or cranial diabetes insipidus) limit fluid intake to a maximum of 500 ml to quench thirst from 1 hour before until 8 hours after the dose.

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.

DDAVP/Desmopressin Injection contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'

3. How DDAVP/Desmopressin Injection will be given

Depending on the condition that you are being treated for, the doctor will administer the appropriate dose by injection either just under the skin (subcutaneous), into a muscle (intramuscular) or directly into one of your veins (intravenous).

Diagnosis of diabetes insipidus:
The usual dose for adults and children is 2 micrograms given by injection either just under the skin (subcutaneous) or into a muscle (intramuscular).

Treatment of diabetes insipidus:
By injection either just under the skin (subcutaneous), into a muscle (intramuscular) or directly into one of your veins (intravenous).

Adults: The usual dose is 1 to 4 micrograms given once daily.
Children: Doses from 0.4 micrograms (0.1 ml) may be used.

Renal concentration capacity test (as a test to check if the kidneys are functioning properly):

A single dose of 2 micrograms is given to adults and children by injection either just under the skin (subcutaneous) or into a muscle (intramuscular).

During surgery or following trauma in patients with mild to moderate haemophilia and von Willebrand's disease to increase blood clotting factors:
The dose for adults and children is 0.4 micrograms per kilogram body weight, administered by intravenous infusion (by drip) over a period of 20 minutes. This dose should be given before surgery or following trauma. Further doses may be administered at 12 hourly intervals.

If you are given more of DDAVP/Desmopressin Injection than you should:
As this medicine will be given to you whilst you are in hospital it is unlikely that you will be given too much, however, avoid drinking any more fluid and seek medical advice if you have any concerns.

If you have any further questions on the use of this medicine, as your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Drinking too much fluid 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.

STOP using DDAVP/Desmopressin Injection if you experience:
- signs and symptoms of water retention which can occur if too much fluid is consumed such as: unusually bad or prolonged headache, nausea, vomiting, water intoxication, unexplained weight gain, feeling unwell, stomach pain, muscle cramps, dizziness, confusion, decreased consciousness, generalised or local swelling due to a build-up of fluid (e.g. peripheral, face), and in severe cases brain swelling, brain disease due to decreased blood sodium level, convulsions and coma.
- hypersensitivity reactions, including anaphylactic shock, such as itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing

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

Other possible side effects are listed below, starting with the most common.

Common (may affect up to 1 in 10 people):
- headache
- fast or irregular heart rate (tachycardia)
- flushing
- low blood pressure
- nausea
- fatigue

Rare (may affect up to 1 in 1,000 people):
- dizziness

Very rare (may affect up to 1 in 10,000 people):
- low sodium level in your blood (hyponatraemia)

Not known (frequency cannot be determined on the basis of the available data):
- anaphylactic reaction and other serious allergic conditions
- loss of consciousness
- brain swelling (oedema)
- heart attack, angina, chest pain,
- deep vein thrombosis (e.g. blood clot in the leg), stroke, blood clot in the brain, high blood pressure
- shortness of breath, clot in the lung
- vomiting
- skin rash, hives, redness of the skin, itching
- generalised or local swelling due to a build-up of fluid (e.g. peripheral, face),
- injection/infusion site reactions (including swelling, pain, leakage of fluids into the tissue (extravasation), skin redness, bruising and nodules)
- 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 Injection

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.

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep container in the outer carton in order to protect from light.

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 Injection contains
The active substance is desmopressin acetate. Each 1 ml of the solution contains 4 micrograms of the active ingredient desmopressin acetate.

The other ingredients are sodium chloride, hydrochloric acid and water for injection.

What DDAVP/Desmopressin Injection looks like and contents of the pack
DDAVP/Desmopressin Injection is supplied in clear glass, single use ampoules containing 1 ml of a clear, colourless solution. It is presented in packs of 10 ampoules.

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 03/2018.

FERRING
PHARMACEUTICALS

Date: 02 Sep 2016

Title	Leaflet DDAVP DESMOPRESSIN sol for inj 4mcg/ml amp 10x 1ml IE		
Item Nº	5009000660	**Perigord Nº**	288960
Item version	F-5009000660.01	**Barcode Nº**	5009000660
Proof Nº	04	**E-MS Nº**	3005
Country	IE	**Size (mm)**	180 x 300
Colours	P. Black		

FERRING PHARMACEUTICALS

Name	
Date	
Signature	

Variable Data	Translation
line 1:	
line 2:	
line 3:	