

DDAVP[®] 4 micrograms/ml Injection

(Desmopressin acetate)

PATIENT INFORMATION

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet, you may need to read 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.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Important things that you need to know:

- DDAVP Injection is used
 - to diagnose and treat cranial diabetes insipidus
 - to test kidney function
 - during surgery or following trauma in patients with mild to moderate haemophilia (blood condition) or von Willebrand's disease (blood clotting condition)
 - to treat headache prior to and resulting from a lumbar puncture
 - to test for fibrinolytic response
- You should avoid drinking large amounts of fluid while you are being treated with DDAVP Injection.
- If you experience unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting stop using DDAVP Injection.

In this leaflet:

1. What DDAVP Injection is and what it is used for
2. Before DDAVP Injection is given
3. How DDAVP Injection will be given
4. Possible side effects
5. Storing DDAVP Injection
6. Further information

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

DDAVP Injection is a clear, colourless solution. 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).
- 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 Injection is not suitable for every patient or for the treatment of all types of haemophilia or von Willebrand's disease.*)
- to treat headache prior to or resulting from a lumbar puncture (a procedure to obtain a sample of fluid from the spine for laboratory examination in the investigation of disorders of the nervous system)
- to test for fibrinolytic response (a test to measure the capacity of the body to dissolve blood clots once they have formed)

2. Before DDAVP Injection is given

DDAVP Injection will not be given if you:

- are allergic to any of the ingredients listed in section 6 of this leaflet
- drink unusually large quantities of fluids, including alcohol

DDAVP Injection will not be given for the treatment of lumbar puncture headache or for a renal function test or to test your fibrinolytic response if you:

- have high blood pressure or heart problems
- are taking diuretics (water tablets)

DDAVP Injection will not be given to increase blood clotting factors if you:

- suffer from angina
- suffer from moderate to severe von Willebrand's disease

Please consult your doctor before DDAVP 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. Hyponatremia)
- suffer from serious heart or kidney disease

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

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
- 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. indomethacin or ibuprofen

Taking DDAVP Injection with food or drinks:

- you should avoid drinking large amount of fluid while you are being treated with DDAVP 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. You should only drink enough fluid to satisfy your thirst.
- when used for diagnostic purpose (fibrinolytic response, kidney function, or cranial diabetes insipidus), limit fluid intake to no more than 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 DDAVP Injection 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).

Breast-feeding:

If you are breast-feeding ask your doctor or pharmacist for advice before using DDAVP Injection.

3. How DDAVP 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 daily
Children and infants: Doses from 0.4 micrograms may be used.

Renal function test:

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, children and infants 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.

To treat headache prior to or resulting from a lumbar puncture:

The dose for adults is 4 micrograms by injection either just under the skin (subcutaneous) or into a muscle (intramuscular). This dose can be given prior to lumbar puncture to prevent headache or after lumbar puncture when headache occurs. This dose may be repeated 24 hours later.

Fibrinolytic response test:

The dose for adults and children is 0.4 micrograms per kilogram body weight, administered by injection directly into one of your veins (intravenous) over a period of 20 minutes.

If you are given more of DDAVP 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.

4. Possible side effects

Like all medicines, DDAVP Injection can cause side effects.

STOP USING DDAVP INJECTION 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 headaches
- confusion
- unexplained weight gain
- ankle swelling
- nausea or vomiting

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

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

Most people using DDAVP Injection 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.

If you experience one or more of these side effects or any other undesirable effects, please inform your doctor or pharmacist.

5. Storing DDAVP Injection

DDAVP Injection should be stored in a refrigerator at 2°C to 8°C. Keep container in the outer carton.

Use by date: Do NOT use DDAVP Injection past the expiry date on the packaging. The expiry date refers to the last day of that month.

This product should only be given by a doctor or qualified nurse and will be safely disposed of by them.

6. Further information

Your medicine is called DDAVP Injection.

- it is supplied in clear glass ampoules and each ampoule contains 1ml of a clear, sterile colourless solution.
- each 1ml of the solution contains 4 micrograms of the active ingredient Desmopressin acetate dissolved in water for injection.
- other ingredients in DDAVP Injection are sodium chloride and hydrochloric acid.

Marketing Authorisation Holder:

Ferring Pharmaceuticals Ltd.,
Drayton Hall, Church Road, West Drayton,
UB7 7PS, UK

Manufacturer:

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

DDAVP 4 micrograms/ml Injection PL 03194/0002

This leaflet was last revised in June 2014

DDAVP is a registered trademark.

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Title	Leaflet DDAVP/DESMOPRESSIN sol for inj 4mcg/ml amp 10x 1ml GB		
Item N°	5009000664	Perigord N°	289701
Item version	F-5009000664.01	Barcode N°	5009000664
Proof N°	01	F-MS N°	3006
Country	GB	Size (mm)	180 x 370

Colours Pro Black

FERRING PHARMACEUTICALS

Name

Date

Signature

Variable Data

Translation

line 1:

line 2:

line 3: