PATIENT INFORMATION

REMEMBER: Only a doctor can prescribe this medicine. It should never be given to anyone except the person who has been prescribed it. It may harm them even if they have the same symptoms.

Please read this information leaflet carefully before treatment with the medicine. This leaflet does not contain all information, so if you have any questions or there is anything you are unsure about, please ask your doctor or pharmacist.

ABOUT YOUR MEDICINE

DDAVP/Desmopressin Injection is a clear, sterile aqueous solution. It contains the active ingredient Desmopressin acetate dissolved in water for injection. The solution also contains the inactive ingredients sodium chloride to adjust the concentration and hydrochloric acid to adjust the acidity of the solution to values which are suitable for injection. The solution is packed in clear glass ampoules at a strength of 4 micrograms in 1ml. The ampoules are packed in boxes of 10.

Manufactured by: Ferring GmbH, Witttled 11, D-24109 Keil, Germany.

DDAVP/Desmopressin Injection contains the active ingredient Desmopressin acetate. This is a synthetic substance similar to antidiuretic hormone (ADH) produced naturally in the body. One of its actions is to reduce the amount of urine produced by the kidneys. Desmopressin increases the levels of some of the factors which help the blood clotting process to work more effectively. In order for the blood clotting process to work normally a number of clotting factors are required. Patients with certain bleeding disorders may have low levels of one or more of these clotting factors. DDAVP/Desmopressin Injection may help these patients including those suffering from haemophilia or von Willebrand’s disease.

Uses:

DDAVP/Desmopressin Injection is used:
- for the diagnosis and treatment of cranial diabetes insipidus, a disease which causes extreme thirst and the continuous production of large volumes of dilute urine
- to increase blood clotting factors in patients with mild to moderate haemophilia or von Willebrand’s disease undergoing surgery or following trauma (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)
- to treat headache 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)
- for test fibrinolytic response (a test to measure the capacity of the body to dissolve blood clots once they have formed)

BEFORE TREATMENT WITH THE MEDICINE

If the answer to any of the following questions is YES and the doctor does not know about it, tell the doctor BEFORE treatment with the medicine.

Are you:

- suffering from type IIB von Willebrand’s disease?
- suffering from a severe heart or kidney disease?
- suffering from difficulty passing water?
- pregnant, trying to become pregnant, or breast feeding?
- drinking large amounts during the day or night?
- taking medication for high blood pressure or have been told that your blood pressure is abnormal?
- taking any other medicines that the doctor does not know about, including over the counter medicines?
- on medication for depression or epilepsy?
- taking diuretics (water tablets)
- taking medication for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin?
- suffering from haemophilia or von Willebrand’s disease.
- suffering from difficulty passing water?
- taking medication for high blood pressure or have been told that your blood pressure is abnormal?
- taking any other medicines that the doctor does not know about, including over the counter medicines?
- on medication for depression or epilepsy?
- taking diuretics (water tablets)
- taking medication for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin?
- allergic to any of the ingredients listed?
- suffering from haemophilia or von Willebrand’s disease.

If you are pregnant or planning a pregnancy, please inform your doctor before DDAVP/Desmopressin Injection is used. It is not known if DDAVP/Desmopressin Injection, in usual doses, is harmful to the unborn baby.

PRECAUTIONS AND WARNINGS

Excessive fluid intake may lead to a build up of water which dilutes the salt in the blood. This is a serious problem and may lead to fits. If any of the following symptoms should occur while you are treated with DDAVP/Desmopressin Injection, avoid drinking any more fluid before seeking medical advice. Contact the doctor or nearest casualty department at once before using another dose:

- unexplained weight gain
- an unsteady body or prolonged headache
- nausea and/or vomiting
- confusion

When DDAVP/Desmopressin Injection is used for the diagnosis of diabetes insipidus or for the renal concentration capacity test, fluid intake must be limited and not exceed 500mls from 1 hour before until 8 hours after a dose.

USING YOUR MEDICINE

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).

The usual doses are:

- Treatment of cranial diabetes insipidus:
  - By subcutaneous, intramuscular or intravenous injection.
  - Adults: The usual dose is 1 to 4 micrograms daily.
  - Children and infants: Doses from 0.4 micrograms (0.1ml) may be used.

Diagnosis of cranial Diabetes Insipidus:

- The dose for the diagnosis of cranial diabetes insipidus in adults and children is 2 micrograms given by subcutaneous or intramuscular injection.

Mild to moderate haemophilia and von Willebrand’s disease:

- The dose for adults, children and infants is 0.4 micrograms per kilogram body weight, administered by the intravenous route. Further doses may be administered at 12 hourly intervals so long as covering adequate dose is used.
- The dose should be diluted in 50ml of 0.9% sodium chloride for injection and given over a period of 20 minutes. This dose should be given before surgery or following trauma.

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

- A single dose of 2 micrograms is used for adults and children, administered by the subcutaneous or intramuscular route.

To treat headache resulting from a lumbar puncture:

- By subcutaneous or intramuscular injection.
- Where a headache is thought to be due to a lumbar puncture, an adult patient can be given a dose of 4 micrograms, which may be repeated 24 hours later if necessary. Alternatively, a dose of 4 micrograms can be given (to prevent headache) immediately prior to the lumbar puncture and repeated 24 hours later.

Fibrinolytic Response Testing:

- The dose for adults and children is 0.4 micrograms per kilogram body weight, administered by the intravenous route. The dose should be diluted in 50ml of 0.9% sodium chloride for injection and given over a period of 20 minutes.

Overdose:

If you think you have been given too much DDAVP/Desmopressin Injection, please tell a nurse or doctor. In the event of an overdose, avoid drinking any more fluid and seek medical advice.

SIDE EFFECTS

Side effects include headache, stomach pain and nausea. 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. Treatment with desmopressin without reducing fluid intake may lead to fluid retention, hyponatraemia (dilution of salt in the blood) and in more serious cases, fits.

When DDAVP/Desmopressin Injection is administered into a vein for the treatment of mild to moderate haemophilia or von Willebrand’s disease, a decrease in blood pressure and an increase in the rate of heart beats, together with facial flushing may occur in some patients.

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

STORING YOUR MEDICINE

DDAVP/Desmopressin Injection should be stored in a refrigerator. Do NOT use DDAVP/Desmopressin injection if it is past the expiry date on the packaging.

If you are unsure about the storage, ask your pharmacist. It is best to return all old and unused medication to your doctor for safe disposal.

PLEASE DO NOT THROW THIS LEAFLET AWAY UNTIL THE MEDICINE IS FINISHED, AS IT MAY BE NEEDED AGAIN.

DDAVP/Desmopressin Injection PL 3194/0002

This leaflet was revised in May 2008.

DDAVP is a registered trademark.