

DDAVP Tablets

0.1mg and 0.2mg
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 tablets are used to treat
 - diabetes insipidus (a condition that causes extreme thirst and the continuous production of large volumes of dilute urine)
 - post-hypophysectomy polyuria/polydipsia (extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland).
- You should avoid drinking large amounts of fluid while you are being treated with DDAVP Tablets, 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.
- If you experience unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting STOP USING DDAVP Tablets. You should tell your doctor immediately or go to the casualty department at your nearest hospital.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine.

In this leaflet:

1. What DDAVP Tablets are and what they are used for
2. Before you take DDAVP Tablets
3. How to take DDAVP Tablets
4. Possible side effects
5. How to store DDAVP Tablets
6. Further information

1. What DDAVP Tablets are and what they are used for

DDAVP Tablets are for oral use only. They are available in two strengths, 0.1mg and 0.2mg. They contain Desmopressin acetate, an antidiuretic (reduces urine production). They are used:

- to treat diabetes insipidus (a condition that 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 post-hypophysectomy polyuria/polydipsia (extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland).

2. Before you take DDAVP Tablets

There are general restrictions, precautions and warnings which apply to all patients using DDAVP Tablets.

General restrictions (all patients):

Do not take DDAVP Tablets if you:

- have a serious heart or kidney disease
- are taking diuretics (water tablets)
- are allergic to any of the ingredients listed in section 6 of this leaflet
- drink unusually large quantities of fluids, including alcohol.

You should avoid drinking large amounts of fluid while you are being treated with DDAVP Tablets, 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.

General precautions and warnings (all patients):

Please consult your doctor before taking DDAVP Tablets if you:

- have an illness causing fluid and/or salt imbalance e.g. vomiting, diarrhoea, systemic infections, fever or gastroenteritis
- have a medical condition that could be made worse by fluid and/or electrolyte disturbance. Condition where your blood sodium levels are too low or you are likely to build up too much water in the body

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. indometacin
- are taking a medicine containing loperamide for diarrhoea

Pregnancy:

If you are pregnant or planning a pregnancy, please inform your doctor before you take DDAVP Tablets, 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 taking DDAVP Tablets.

DDAVP Tablets contain Lactose monohydrate:

DDAVP Tablets contain the ingredient, lactose monohydrate. Therefore, if you have been told by your doctor that you have an intolerance to some sugars (including lactose), contact your doctor before taking this medicinal product.

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3. How to take DDAVP Tablets

DDAVP Tablets are for oral use only.

Do NOT take more than the prescribed dose in any 24 hour period.

If you have the impression that the effect of DDAVP Tablets is too strong or too weak, talk to your doctor or pharmacist.

The usual doses are:

Treatment of diabetes insipidus:

Your doctor will prescribe the dose most suitable for you. The most common dose in adults and children is one 0.1mg tablet or one 0.2mg tablet taken three times a day.

Treatment of extreme thirst and the continuous production of large volumes of dilute urine following surgical removal of the pituitary gland:

Your doctor will prescribe the most suitable dose for you based on the concentration of your urine.

If you take more DDAVP Tablets than you should:

If you take more DDAVP Tablets than you should, talk to your doctor or pharmacist immediately.

If you forget to take DDAVP Tablets:

Do not take a double dose to make up for a forgotten dose. If you are a patient with diabetes insipidus, please consult your doctor or pharmacist for advice.

4. Possible side effects

Like all medicines, DDAVP Tablets can have side effects.

You should avoid drinking large amounts of fluid while you are being treated with DDAVP Tablets, 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.

STOP USING DDAVP Tablets if you experience:

- unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting
- itching, skin rashes, swelling of the face, lips or throat, difficulty in breathing, wheeziness, chest tightness or coughing (signs of allergic reaction)

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

Most people taking DDAVP Tablets 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 Tablets

Keep DDAVP Tablets out of the reach and sight of children.

Do not store above 25°C. Keep the container tightly closed.

Do not remove the silica gel insert from the bottle top.

Do not take past the expiry date on the packaging. The expiry date refers to the last day of that month.

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

6. Further Information

- DDAVP Tablets are presented in plastic bottles containing either 30 or 90 tablets
- each tablet contains either 0.1mg or 0.2mg of the active ingredient, Desmopressin acetate other ingredients in DDAVP Tablets are lactose monohydrate, potato starch, povidone and magnesium stearate
- The 0.1mg tablets are white, oval tablets, scored on one side and engraved '0.1' on the other side. The 0.2mg tablets are white, round tablets, scored on one side and engraved '0.2' on the other side.

Marketing Authorisation Holder:

Ferring Pharmaceuticals Ltd.,
Drayton Hall, Church Road,
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Manufacturer:

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

DDAVP Tablets 0.1mg
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DDAVP Tablets 0.2mg
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This leaflet was last revised in October 2011.

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