

Desmopressin Acetate 0.2 mg Tablets

Your medicine is known as Desmopressin Acetate 0.2 mg Tablets but will be referred to as Desmopressin Acetate Tablets throughout the following leaflet

Information for another strength of Desmopressin acetate tablets (0.1 mg) is also present in this leaflet.

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 might 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.

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1. What Desmopressin Acetate Tablets are and what they are used for
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1. WHAT DESMOPRESSIN ACETATE TABLETS ARE AND WHAT THEY ARE USED FOR

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

They are used:

- to treat primary nocturnal enuresis (bedwetting) in children (from 5 years of age) and adults (up to 65 years of age)
- to treat cranial 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 DESMOPRESSIN ACETATE TABLETS

Do not take Desmopressin Acetate Tablets:

- if you have a serious heart or kidney disease
- if you are taking diuretics (water tablets)
- if you are allergic to any of the ingredients listed in section 6 of this leaflet
- if you drink unusually large quantities of fluids, including alcohol
- for bedwetting, these tablets should not be used if you are under 5 years old or over 65 years old
- for bedwetting, if you have high or low blood pressure

Take special care with Desmopressin Acetate Tablets:

- if you have an illness causing fluid and/or electrolyte imbalance e.g. vomiting, diarrhoea, systemic infections, fever, gastroenteritis
- if you have a medical condition that could be made worse by fluid and/or electrolyte disturbance
- if you have cystic fibrosis

If any of these apply to you, or if you are not sure, contact your doctor before taking Desmopressin Acetate Tablets.

Taking Desmopressin Acetate Tablets with food or drink:

- fluid intake must be limited to a minimum from 1 hour before taking the dose at bedtime until the following morning (and, in any case, for at least 8 hours)
- avoid swallowing water while swimming to prevent a build up of water in the body.
- You should avoid drinking large amount of fluid while you are being treated with Desmopressin Acetate Tablets, 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 fits.

Taking/using other medicines:

Please inform your doctor or pharmacist:

- if you are taking or have recently taken any other medicines, including medicines obtained without a prescription
- if you are on medication for depression or epilepsy
- if you are taking a medicine for pain and/or inflammation containing nonsteroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin
- if you are taking a medicine containing loperamide, for diarrhoea

Pregnancy:

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

Desmopressin Acetate Tablets contain Lactose monohydrate:

Desmopressin Acetate 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.

3. HOW TO TAKE DESMOPRESSIN ACETATE TABLETS

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

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

The usual doses are:

Bedwetting from the age of 5 years and up to 65 years old:

Your usual starting dose is one 0.2 mg tablet at bedtime. Your doctor may increase the dose to two 0.2 mg tablets at bedtime depending on how well the bedwetting is controlled. The need for continued treatment is normally checked every three months.

Treatment of diabetes insipidus:

Your doctor will prescribe the dose most suitable for you. The most common dose in adults and children is one 0.1 mg tablet or one 0.2 mg 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 Desmopressin Acetate Tablets than you should:

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

If you forget to take Desmopressin Acetate Tablets:

Do not take double doses to make up for forgotten doses.

If you are a patient being treated for bedwetting, do not take Desmopressin Acetate Tablets 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

Like all medicines, Desmopressin Acetate Tablets can cause side effects.

- Low levels of sodium in your blood can lead to fits. This is more likely to happen if you drink large amounts of fluid while receiving this medication.
- If you experience unusually bad or prolonged headache, confusion, unexplained weight gain, ankle swelling, nausea or vomiting, stop using Desmopressin Acetate Tablets.
You should tell your doctor immediately or go to the casualty department at your nearest hospital.

Most people taking Desmopressin Acetate Tablets find it causes them no problems.

However, side effects can include:

- headache
- stomach pain

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 also been reported.

If you experience one or more of these side effects or any other side effects not listed in the leaflet, please contact your doctor or pharmacist immediately.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DESMOPRESSIN ACETATE TABLETS

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 25°C.
- Store in the original container to protect from moisture. Keep the bottle tightly closed.
- Do not remove the silica gel insert from the bottle top
- Do not use this medicine after the expiry date that is stated on the labels after EXP. The expiry date refers to the last day of that month.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Desmopressin Acetate Tablets contains

- The active ingredient is desmopressin acetate.
Each tablet contains 0.2 mg of desmopressin acetate.
- The other ingredients are lactose monohydrate, potato starch, povidone and magnesium stearate.

What Desmopressin Acetate Tablets looks like and contents of the pack

- Desmopressin Acetate Tablets are white, round, convex tablets, scored on one side and engraved '0.2' on the other side.
- The tablets are presented in plastic bottles containing either 30 or 3x30 tablets.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by Ferring GmbH, Wittland 11, D-24109 Kiel, Germany.

POM PL: 19488/1877

Leaflet revision date: 03 November 2020

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S1877 LEAFLET Desmepressin acetate 20201103