Desmopressin Acetate 0.1mg Tablets

Package leaflet; information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again
• If you have further questions, ask your doctor or pharmacist
• 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
• This medicine is available in another strength and may be referred to throughout the leaflet.

What is in this leaflet:
1. What Desmopressin acetate is and what it is used for
2. What you need to know before you take Desmopressin acetate
3. How to take Desmopressin acetate
4. Possible side effects
5. How to store Desmopressin acetate
6. Contents of the pack and other information

What is Desmopressin acetate and what it is used for
The ingredient that makes the tablet work (the active substance) is called desmopressin. Desmopressin is an antidiuretic, which reduces the amount of urine produced by the kidneys. Desmopressin acetate is used to treat:
• a chronic disease called diabetes insipidus which causes extreme thirst and continuous production of large volumes of dilute urine. Important: Not to be confused with diabetes mellitus (sugar diabetes)
• bed-wetting in children (involuntary nightly urination) older than 5 years
• frequent urination during the night in adults (nocturia). Please read section 2 carefully for important information on the safe use of Desmopressin acetate in this case.
• This medicine is available in another strength and may be referred to throughout the leaflet.

What you need to know before you take Desmopressin acetate
Do not take Desmopressin acetate:
• If you are allergic to active substance or any of the other ingredients of this medicine (listed in section 6)
• If you drink unusually large amounts of fluid
• If you suffer from heart problems or other diseases needing treatment with diuretics (water tablets)
• If you suffer from reduced kidney function
• If you know you have low level of sodium in your blood (hyponatraemia)
• If you suffer from the Syndrome of Inappropriate Secretion of Antidiuretic Hormone* (SIADH)
• If you suffer from Von Willebrand’s disease type IIB (hereditary bleeding disorder)
• If you suffer from a rare blood disorder called Thrombotic thrombocytopenic purpura (TTP).

Warnings and precautions
Talk to your doctor or pharmacist before taking Desmopressin acetate:
• In connection with fluid intake. Keep your fluid intake to a minimum from 1 hour before you take a tablet until 8 hours after a dose
• Tell your doctor before taking Desmopressin acetate if you have cystic fibrosis as your doctor will need to monitor your blood sodium level
• If you are elderly
• If you have a medical condition causing fluid and/or electrolyte imbalance in the body, such as an infection, fever or stomach upset
• If you suffer from a serious bladder problem or impaired urine outflow
• If you suffer from asthma, epilepsy and migraine.

Other medicines and Desmopressin acetate
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially:
• tricyclic or SSRI antidepressants (used to treat depression)
• carbamazepine (used to treat epilepsy)
• chlorpromazine (used to treat psychosis or schizophrenia)
• loperamide (used to treat diarrhoea)

medicines for pain and/or inflammation called non-steroidal anti-inflammatory drugs (NSAIDs) e.g. indometacin, ibuprofen.

These medicinal products increase the risk of build-up of water, which dilutes the salt in the body. dimeticone (used in the treatment of symptoms due to intestinal gas), due to decreased absorption of desmopressin.

Taking Desmopressin acetate with food and drink
• Do not take Desmopressin acetate with food, as the effect of the tablets may be reduced
• Before you start treatment with this medicine, your doctor should give you advice about fluid intake
• When using this medicine for bed-wetting or nocturia, keep your fluid intake to a minimum from 1 hour before you take a tablet until 8 hours after a dose
• Too much fluid intake may lead to a build-up of water, which dilutes the salt in the body. This can occur with or without warnings or symptoms, which include unusually bad or prolonged headache, feeling or being sick, unexplained weight gain and in serious cases, fits and unconsciousness. If you have any of these symptoms, stop the treatment and contact your doctor at once.

Pregnancy, breast-feeding 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.”

Desmopressin acetate can be used during pregnancy and breast-feeding only if prescribed by a doctor. Only limited experience from use of Desmopressin acetate in pregnant women with diabetes insipidus exists.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
There is no evidence to suggest that Desmopressin acetate affects the ability to drive and use machines.

Desmopressin acetate contains lactose
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, then please contact your doctor before taking this medicinal product.

How to take Desmopressin acetate
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Desmopressin acetate treatment of frequent urination during the night in adults (nocturia) should be started and controlled by specialists with experience in this treatment.

(continued overleaf)
• Divide the tablets in half or swallow whole. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.
• Do not take Desmopressin acetate with food, as the effect of the tablets may be reduced.
• During treatment with Desmopressin acetate your body weight, the sodium level in your blood and/or blood pressure should be monitored regularly.

The recommended dose
• Central diabetes insipidus
  Adults and children: 100 micrograms (0.1mg) three times a day. Your doctor may increase the dose depending on how well your symptoms are controlled.
• Bed-wetting (involuntary nightly urination)
  Children under 5 years: 200 micrograms (0.2mg) at bedtime. Your doctor may increase the dose up to 400 micrograms (0.4mg) at bedtime depending on how well the bed-wetting is controlled. The need for continued treatment is normally checked every three months by introducing a treatment free period of at least one week.
• Frequent urination during the night (nocturia)
  Adults: 100 micrograms (0.1mg) at bedtime. The dose may be increased to 200 micrograms (0.2mg) and subsequently up to a maximum of 400 micrograms (0.4mg) with 1-week intervals. Before starting treatment your urine production should be measured. If nocturia is not improved after four weeks, see your doctor as the treatment should be stopped.
  Elderly: treatment for nocturia in the elderly is not recommended. If the doctor decides to treat you, your blood sodium levels should be measured before and three days after starting the treatment and if the dose is increased or at any time your doctor finds it necessary.

When using this medicine for bed-wetting or nocturia keep your fluid intake to a minimum from 1 hour before you take a tablet until 8 hours after a dose.

If you take more Desmopressin acetate than you should
An overdose may lengthen the effect of desmopressin and increase the risk of water build-up in the body and low levels of sodium in your blood. Symptoms of severe water build-up include fits and unconsciousness. If you take more Desmopressin acetate than prescribed, contact your doctor, pharmacist or the nearest hospital at once.

If you forget to take Desmopressin acetate
Do not take a double dose to make up for a forgotten dose.
If you stop taking Desmopressin acetate
You should only change or stop your treatment if advised by your doctor.

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

4 Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Stop the treatment and contact your doctor at once if the following occur:
• symptoms of a build-up of water in the body such as unusually bad or prolonged headache, feeling or being sick, unexplained weight gain and in serious cases, fits, unconsciousness
• allergic reactions such as rash, itching, fever, swelling of the mouth, tongue or airways causing difficulties in swallowing or breathing.

Tell your doctor or pharmacist if you notice any of the following other side effects:
• Very common may affect more than 1 in 10 people: headache
  • Common may affect up to 1 in 10 people: dry mouth, abdominal pain, feeling sick, dizziness, swelling of arms and legs, weight gain, frequent urination
  • Very rare may affect up to 1 in 10,000 people: emotional disturbances in children, allergic reactions
  • Not known frequency cannot be estimated from the available data: build-up of water in the body, low levels of sodium.

Reporting of side effects
If you get 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. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Desmopressin acetate
Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP.
The expiry date refers to the last day of that month. Do not store above 30°C. Keep the bottle tightly closed in order to protect from moisture.

If your tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.
Do not throw away 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 Contents of the pack and further information
What Desmopressin acetate contains
• The active substance is desmopressin acetate. Each tablet contains 0.1mg desmopressin acetate equivalent to 0.089mg desmopressin.
• The other ingredients are lactose monohydrate, maize starch, povidone, starch pregelatinised, silica, colloidal anhydrous and magnesium stearate.

What Desmopressin acetate looks like and contents of the pack
Desmopressin acetate 0.1mg tablets are white, biconvex, oval tablets with the inscription ‘D’, score mark and ‘0.1’ on the one side and plain on the other side.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
They are packed in 30ml white opaque PE bottles with a white opaque PP cap with desiccant and child-resistant closure. Desmopressin 0.1mg tablets are available in packs of 90 tablets.

PL holder: Manx Healthcare Ltd, Taylor Group House, Wedgwood Lane, Warwick, CV34 5YA
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POM

Manufacturer: Pharmachemie B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands
To request a copy of this leaflet in large print, audio or Braille, please call 01926 462511

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