Package Leaflet: Information for the user

Nordurine 0.1 mg Tablets
Nordurine 0.2 mg Tablets
Desmopressin Acetate

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 use it again
- If you have any 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 or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

In this leaflet:

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

Nordurine 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 that reduces urine production.

Nordurine Tablets are used to treat:
- **Diabetes Insipidus** (extreme thirst and the continuous production of large volumes of dilute urine). IMPORTANT: this should not be confused with diabetes mellitus (sugar diabetes)
- **Primary nocturnal enuresis** (bedwetting from the age of five)
- **Nocturia** in adults up to 65 years (night time urine production exceeding bladder capacity)

2. What you need to know before you take Nordurine Tablets

Do not take Nordurine Tablets
- if you are allergic to desmopressin or any of the other ingredients of this medicine (listed in section 6)
- if you have a serious heart or kidney disease
- if you are taking diuretics (water tablets)
- if you drink unusually large quantities of fluids, including alcohol
- for Primary Nocturnal Enuresis and Nocturia: these tablets should not be used if you are under 5 years old or over 65 years old
- if you have known hyponatraemia (serum sodium levels below normal range)
- if you have syndrome of inappropriate secretion of anti-diuretic hormone, a hormone regulating urine production (SIADH)

Warnings and precautions
Talk to your doctor or pharmacist before taking Nordurine Tablets

Take special care with Nordurine 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 you have difficulty in passing water
- for Primary Nocturnal Enuresis and Nocturia: STOP using Nordurine Tablets when suffering from vomiting and diarrhoea until you are better.

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

Other medicines and Nordurine Tablets:
Tell your doctor or pharmacist:
- if you are taking, have recently taken or might take any other medicines
- if you are on medication for depression, epilepsy or type II diabetes
- if you are taking a medicine for pain and/or inflammation containing non-steroidal anti-inflammatory drugs (also known as NSAIDs) e.g. indomethacin
- if you are taking a medicine containing loperamide, for diarrhoea

Nordurine Tablets with food or drink:
- For Primary Nocturnal Enuresis and Nocturia: 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)
- You should avoid drinking large amounts of fluid while you are being treated with Nordurine 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.
- At low doses of Desmopressin, simultaneous food intake may reduce the intensity and duration of the antidiuretic effect of Nordurine Tablets.

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 you doctor or pharmacist for advice before taking this medicine.

Nordurine Tablets contain lactose
Nordurine Tablets contain the ingredient, lactose monohydrate. 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 Nordurine Tablets

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

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

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

Diabetes Insipidus:
Your doctor will prescribe the dose most suitable for you. The most common dose is one 0.1 mg tablet or one 0.2 mg tablet taken three times a day.

Bedwetting from the age of 5 years:
Your usual starting dose is one 0.2 mg tablet at bedtime. Your doctor may increase the dose to two 0.2 mg tablets (0.4 mg) at bedtime depending on how well the bedwetting is controlled. Do not drink until morning. The need for continued treatment is normally checked every three months.

Nocturia
Your usual starting dose is one 0.1mg tablet at bedtime. This dose may be increased after one week to 0.2 mg and increased weekly thereafter to 0.4 mg as your doctor recommends. Please refer to the paragraph, **Nordurine Tablets with food or drink** in Section 2 for information regarding fluid intake.

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

If you forget to take Nordurine Tablets
DO NOT TAKE A DOUBLE DOSE to make up for a forgotten dose.

If you are a patient being treated for Primary Nocturnal Enuresis or Nocturia, do not take Nordurine 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.

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4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

- 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, abdominal pain, nausea, vomiting, unexplained weight gain, dizziness, confusion, feeling of general discomfort, memory impairment, feel a whirling or spinning (vertigo) or falls STOP using Nordurine Tablets.

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

Other side effects associated with Nordurine Tablets are listed below, starting with the most common.

The following common side effects may affect up to 1 in 10 people:
Adults:
- increased blood pressure
- diarrhoea, constipation
- urinary symptoms
- fatigue
- swelling due to the build up of fluid

The following uncommon side effects may affect up to 1 in 100 people:
Adults:
- trouble sleeping, sleepiness
- numbness, tingling, burning or creeping on the skin (paresthesia)
- visual impairment
- feeling of abnormal heart beat (palpitations)
- low blood pressure
- shortness of breath (dyspnoea)
- upset stomach, indigestion, flatulence, bloating
- sweating, itchy, rash, hives
- muscle spasms, muscle pain
- chest pain
- influenza-like illness
- changes in liver function
- low blood potassium

Children and Adolescents:
- emotional instability
- aggression
- diarrhoea
- urinary symptoms
- fatigue
- swelling due to a build up of fluid

The following rare side effects may affect up to 1 in 1,000 people
Adults:
- allergic skin reactions

Children and Adolescents:
- symptoms of anxiety
- nightmares
- mood swings
- sleepiness
- high blood pressure
- irritability

The frequency of the following side effects cannot be estimated from the available data:
Adults:
- anaphylactic reaction
- convulsions
- coma
- *Diabetes Insipidus indication only:* high blood sodium, dehydration, weakness

Children and Adolescents:
- anaphylactic reaction
- abnormal behaviour
- emotional disorder
- depression
- hallucination
- trouble sleeping
- disturbance in attention
- increased restlessness and movement
- convulsions
- nose bleeds
- allergic skin reactions, rash, sweating, hives

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nordurine Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C. Store in the original package and keep the bottle tightly closed in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nordurine Tablets contain
The active substance is desmopressin acetate. Each tablet contains either 0.1 mg or 0.2 mg of the active ingredient, desmopressin acetate

The other ingredients are lactose monohydrate, potato starch, povidone and magnesium stearate.

What Nordurine Tablets look like and contents of the pack
Nordurine 0.1 mg Tablets are white, oval, convex tablets, scored on one side and engraved '0.1' on the other side. Nordurine 0.2 mg Tablets are white, round, convex tablets, scored on one side and engraved '0.2' on the other side.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The tablets are presented in plastic bottles containing either 30 or 90 tablets.

Marketing Authorisation Holder:
Ferring Ireland Ltd., United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24.

Manufacturer:
Ferring GmbH, Wittland 11, D-24109 Kiel, Germany.

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FERRING
PHARMACEUTICALS

1162 St-Prex
Switzerland
Nathalie Chateau

Item No : *2009053183*
Title :

Leaflet NORDURINE tab oral bottle IE

E-MS No : *3002*
Barcode : *1819*
Date : *2014-02-24*
Proof version : *4*
Braille ☐
Perforation ☐ vignette ☐ other
Format (mm) : *140x480*
Colours : *Black*

Variable data line 1 (eng) :
Variable data line 2 (eng) :
Variable data line 3 (eng) :
Country :
Name :
Date :
Signature :