Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Minirin tablets 0.1 mg

Minirin tablets 0.2 mg

Composition:
Each tablet of Minirin 0.1 mg contains:
desmopressin acetate 0.1 mg
Each tablet of Minirin 0.2 mg contains:
desmopressin acetate 0.2 mg

Inactive ingredients - see section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Diabetes insipidus, nocturnal enuresis, nocturia in adults related to excessive nocturnal urine production.
Therapeutic group: vasopressin hormone analog

2. Before using this medicine

Do not use this medicine:

- if you are sensitive (allergic) to desmopressin or to any of the other ingredients of this medicine (see section 6).
- if you have a serious heart or kidney disease.
- if you are taking diuretics.
- if you drink unusually large quantities of fluids, including alcohol.
- upon administration for nocturnal enuresis and nocturia: if you are under 5 years old or over 65 years old.
- if you have low blood sodium levels (hyponatremia).
- if you have a medical condition with increased secretion of ADH (syndrome of inappropriate secretion of ADH).

During treatment with the medicine, refrain from drinking large quantity of fluids. Drinking large quantity of fluids may cause accumulation of water and dilution of salt concentration in the body. This is a severe medical problem which may lead to convulsions.

Special warnings about using this medicine:

Before using the medicine, tell your doctor if you suffer from:

- an illness causing fluid and/or electrolyte imbalance, e.g. vomiting, diarrhea, systemic infections, fever or gastroenteritis
- a medical condition which may worsen in case of fluid and/or electrolyte imbalance
- cystic fibrosis

- difficulty urinating

During treatment with the medicine for nocturnal enuresis and nocturia

- Stop taking the medicine when suffering from vomiting and diarrhea until your health improves.
- Fluid intake must be limited to a minimum starting from 1 hour before taking Minirin in the evening until the following morning (at least 8 hours).

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines for treatment of depression, epilepsy or type II diabetes.
- medicines containing loperamide (against diarrhea).
- medicines of the NSAIDs class (non-steroidal anti-inflammatory drugs for treatment of pain and/or inflammatory conditions, e.g. indomethacin).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before taking this medicine.

Driving and using machines:

The medicine has no or negligible effect on the ability to drive and/or operate machines.

Important information about some of this medicine's ingredients:

The tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars (including lactose), consult your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

- Diabetes insipidus
  The initial dose is usually 0.1 mg three times a day. The dose is subsequently adjusted according to the patient's response. Most patients will receive a dose of 0.1-0.2 mg three times a day.

- Nocturnal enuresis
  The initial dose is usually 0.2 mg before bedtime. If this dose is insufficient, your doctor may increase the dose to 0.4 mg.

- Nocturia
  The initial recommended dose is 0.1 mg before bedtime. If this dose is insufficient, after 1 week your doctor may increase the dose to 0.2 mg, followed by weekly dose elevations to 0.4 mg.

Do not exceed the recommended dose.

If you have accidentally taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose to compensate for the forgotten dose.
If you are taking Minirin for treatment of nocturnal enuresis or nocturia, do not take your next dose until the usual time for your next dose.
If you are taking Minirin for treatment of diabetes insipidus, consult your doctor.
Do not take more than one prescribed dose in 24 hours.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Minirin tablets may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Low sodium levels in your blood may cause convulsions. This is more likely to happen if you drink a large amount of fluids while being treated with this medicine.

Contact your doctor or go to the nearest hospital immediately if you experience:

- a very intense or prolonged headache, abdominal pain, confusion, unexplained weight gain, nausea, vomiting, dizziness, feeling of general discomfort, memory impairment, feeling that you are whirling, spinning (vertigo) or falling.

Additional side effects:

<u>Common side effects (effects occurring in 1-10 in 100 users)</u>
Adults:

- increased blood pressure
- diarrhea, constipation
- urinary symptoms
- fatigue
- swelling due to fluid accumulation

<u>Uncommon side effects (effects occurring in 1-10 in 1,000 users)</u>
Adults:

- trouble sleeping, sleepiness
- numbness, tingling, burning or creeping on the skin (paresthesia)
- vision impairments

- feeling of abnormal heart beats (palpitations)
- low blood pressure
- shortness of breath (dyspnea)
- stomach problems, indigestion, flatulence, bloating
- sweating, itching, rash, hives
- muscle spasms, muscle pain
- chest pain
- flu-like symptoms
- change in liver function
- low blood potassium levels

Children and adolescents:

- aggression
- emotional instability
- diarrhea
- urinary symptoms
- swelling due to fluid accumulation
- fatigue

Rare side effects (effects occurring in 1-10 in 10,000 users)

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 reactions (severe allergic reactions)
- convulsions
- coma
- only in diabetes insipidus: high blood sodium levels, dehydration, weakness

Children and adolescents:

- anaphylactic reactions (severe allergic reactions)
- abnormal behavior
- emotional disorders
- depression
- hallucinations
- insomnia
- attention disorders
- increased restlessness and movement
- convulsions
- nosebleed
- allergic skin reactions, rash, sweating, hives

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25˚C in its original packaging.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Lactose monohydrate, potato starch, povidone, magnesium stearate

What the medicine looks like and contents of the pack:
Minirin tablets 0.1 mg: a white, oval and convex tablet, scored on one side and engraved '0.1' on the other side.
Minirin tablets 0.2 mg: a white, oval and convex tablet, scored on one side and engraved '0.2' on the other side.

The medicines are supplied in packs containing 30 tablets.

Registration holder's name and address:
Ferring Pharmaceuticals Ltd., 8 Hashita St., Industrial Park, Caesarea 3088900.

Manufacturer’s name and address:
Ferring International Center SA, Switzerland.

This leaflet was revised in February 2023, in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Minirin tablets 0.1 mg: 141 99 25705
Minirin tablets 0.2 mg: 141 98 25704