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

Noqdirna 25
Dispersible tablets for sublingual administration

Active ingredient and its quantity:
Noqdirna 25:
Each tablet contains:
desmopressin (as acetate) 25 mcg

Noqdirna 50
Dispersible tablets for sublingual administration

Active ingredient and its quantity:
Noqdirna 50:
Each tablet contains:
desmopressin (as acetate) 50 mcg

For the list of inactive ingredients, please see section 6.

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 for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

- **Noqdirna may cause a decrease in your blood sodium levels (hyponatremia). Severe hyponatremia can be life-threatening, leading to seizures, coma, breathing difficulties or death.**
- **Do not take Noqdirna if you are at risk of severe hyponatremia, such as excessive fluid intake, illness that may cause fluid or electrolyte imbalances in the body, you are taking diuretics or steroids, including inhaled steroids.**
- **Ensure that you are not taking other medicines that may increase the risk of hyponatremia.**
- **Ensure that your blood sodium level is normal before starting treatment. Do not start treatment if the sodium level is below 135 mmol/L.**
  Repeat the test of blood sodium level within 7 days and approximately 1 month after initiating therapy. Monitor blood sodium level periodically during treatment. Monitor blood sodium level more frequently if you are 65 years of age and older or are at risk of severe hyponatremia.
- **Do not continue treatment in case of hyponatremia (sodium levels below 135 mmol/L). In such case, the treatment must be temporarily or permanently discontinued.**

1. What is this medicine intended for?
Noqdirna is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Therapeutic group: a synthetic analog of vasopressin.

There are several possible causes for nocturia, the doctor will verify nocturnal polyuria.
The doctor will instruct the patient to perform a 24-hour urine collection to verify the diagnosis.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (desmopressin) or to any of the other ingredients in this medicine (see section 6).
- You suffer or have suffered from hyponatremia (low sodium level in your blood).
- You are thirsty most of the time and drink plenty of fluids (polydipsia).
- You are taking loop diuretics.
- You are taking oral or inhaled glucocorticoids.
- You suffer from moderate or severe renal disease.
- You suffer from syndrome of inappropriate antidiuretic hormone (SIADH) secretion.
- You suffer from an illness that may cause a decrease in the level of fluids or electrolytes in your blood such as vomiting, diarrhea, infection or a kidney problem resulting in reduced electrolyte level in your blood.
- You suffer from heart failure.
- You suffer from uncontrolled hypertension.

Special warnings about using this medicine

Before treatment with Noqdirna, it is particularly important to tell your doctor if:

- You are at risk of low electrolyte level in your blood
- You have recently suffered from vomiting, diarrhea, fever or infection
- You suffer from heart or kidney problems
- You suffer from hypertension
- You suffer from increased intracranial pressure
- You have suffered from urinary bladder voiding problem in the past
- You are 65 years of age and older. You are at increased risk of hyponatremia

During treatment with the medicine:

- **Noqdirna may cause a decrease in your blood sodium levels (hyponatremia). Severe hyponatremia can be life-threatening, leading to seizures, coma, breathing difficulties or death.**
- **Do not take Noqdirna if you are at risk of severe hyponatremia, such as excessive fluid intake, illness that may cause fluid or electrolyte imbalances in the body, you are taking diuretics or steroids, including inhaled steroids.**
- **Ensure that your blood sodium level is normal before starting treatment. Do not start treatment if the sodium level is below 135 mmol/L.**

Children and adolescents

This medicine is not intended for children and adolescents below the age of 18.
There is no information regarding the safety and efficacy of this medicine in children and adolescents below the age of 18.

Tests and follow up

The doctor will have to monitor your blood sodium level before starting treatment. The doctor will start treatment only if the levels are normal. **Do not start treatment if the sodium level is below 135 mmol/L.**
Repeat the test of blood sodium level after the first week of treatment (7 days after initiating therapy) and again approximately 1 month after initiating therapy.

Subsequently sodium level tests should be performed periodically; the test should be performed more frequently in patients 65 years of age and older or those who are at high risk of hyponatremia.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly important to tell your doctor or pharmacist if you are taking:
- Diuretics.
- Steroids, including inhaled steroids. The doctor will instruct you to stop treatment with Noqdirna during the period of treatment with steroids or immediately afterwards.
- Antidepressants such as tricyclic antidepressants or selective serotonin reuptake inhibitors (SSRIs).
- A medicine for treatment of mood disorders such as schizophrenia or bipolar disorder called chlorpromazine.
- A medicine for treatment of seizures, neuropathic pain or bipolar disorder called carbamazepine.
- Nonsteroidal anti-inflammatory drugs (NSAIDs).

Using this medicine and alcohol consumption
Avoid drinks containing alcohol before bedtime, since this leads to increased urine output.

Pregnancy and breastfeeding
Pregnancy
If you are pregnant, may become pregnant or plan to become pregnant, consult your doctor or pharmacist before taking this medicine. It is not known whether Noqdirna can harm your baby. Noqdirna is not intended for the treatment of normal pregnancy symptoms causing excessive nocturia.
Breastfeeding
Desmopressin, the active ingredient of Noqdirna, passes into breast milk. There is no information on the effect of desmopressin on breastfed infants or on milk production.
The doctor will decide if you can use this medicine during pregnancy or breastfeeding, considering the necessity of treatment against possible risks.

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:
- Women: 25 microgram per day, 1 hour before bedtime, administered sublingually without water. Keep the tablet under the tongue until it has dissolved.
- Men: 50 microgram per day, 1 hour before bedtime, administered sublingually without water. Keep the tablet under the tongue until it has dissolved.

You should limit your fluid intake from 1 hour before taking Noqdirna until 8 hours after taking Noqdirna. You may suffer from severe side effects if you drink too much fluids. Avoid drinks containing caffeine and alcohol before bedtime, since this leads to increased urine output. Void the bladder before bedtime.

Do not exceed the recommended dose.

Crushing/splitting/chewing
The medicine is intended for sublingual administration. There is no information about crushing/splitting/chewing the tablets.

If you have accidentally taken a higher dose
If you have 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**.** Symptoms of overdose may include nausea, headache, drowsiness, confusion, and rapid weight gain due to fluid retention.

If you forget to take the medicine
Do not take a double dose to compensate for the forgotten dose. Continue taking the medicine as usual on the next day.
Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine
Consult your doctor before stopping the treatment.

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. <u>Side effects</u>
Like with all medicines, using Noqdirna may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking the medicine and contact a doctor immediately if you experience one or more of the following symptoms of low blood sodium level (hyponatremia): headache, nausea or vomiting, sensation of restlessness, fatigue, dizziness, drowsiness, muscle cramps, changes in the state of consciousness such as hallucinations, confusion, decreased awareness or alertness.

Additional side effects
Most common side effects include:
- dry mouth
- reduced blood sodium level (hyponatremia) – dizziness
- headache

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. <u>How to store the medicine?</u>
- 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 the original package to protect from moisture and light.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Gelatin, mannitol, citric acid anhydrous.

What the medicine looks like and contents of the pack:
Noqdirna 25:
White, round tablet with “25” embossed on one side.

Noqdirna 50:
White, round tablet with “50” embossed on one side.

Each pack contains 10, 30 or 90 tablets packed in a perforated blister.
Not all pack sizes may be marketed.

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

Manufacturer’s name and address:
Ferring GmbH, Kiel, Germany

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Noqdirna 25: 165-48-35158
Noqdirna 50: 165-49-35159

Revised in 12/2020.