Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Minirin Melt 60 mcg

Minirin Melt 120 mcg

Tablets for sublingual administration

Active ingredients

Minirin Melt 60 mcg -

Each tablet contains 60 mcg desmopressin free base (added as desmopressin acetate)

Minirin Melt 120 mcg -

Each tablet contains 120 mcg desmopressin free base (added as desmopressin acetate)

Inactive ingredients and allergens - 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?

The medicine is intended for treatment of bedwetting (nocturnal enuresis).

Therapeutic group: synthetic vasopressin 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 in this medicine (see section 6)
- you have a severe heart or kidney disease
- you are taking diuretics
- you drink very large quantities of liquids, including alcohol
- you are below the age of 5 or above the age of 65
- you have low blood sodium levels (hyponatremia)
- you have a medical condition associated with increased ADH secretion (abnormal ADH secretion syndrome)

Avoid drinking large quantity of fluids during treatment with the medicine. Drinking large quantity of fluids may lead to water accumulation and dilution of the concentration of salts in the body. This may cause headache, nausea/vomiting, weight gain and in severe cases convulsions.

Special warnings about using this medicine

Before treatment with the medicine, tell your doctor if you have:

- A disease causing impaired fluid and/or electrolyte balance. For example vomiting, diarrhea, systemic infections, fever or gastrointestinal inflammation
- A medical condition which may worsen in case of impaired fluid and/or electrolyte balance. A condition of extremely low sodium levels in your body with a tendency to accumulate excessive quantities of fluids in your body
- Cystic fibrosis
- Urination difficulties

During treatment with the medicine

- Stop taking the medicine in case of vomiting and/or diarrhea until your condition improves
- Your fluid consumption should be limited to a minimum from 1 hour before taking Minirin Melt in the evening till the next morning (and in any case for at least 8 hours)

Minirin Melt with food and drinks: Taking Minirin Melt with food may reduce the duration of action and effect of the medicine.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, particularly if you are taking:

- medicines for treatment of depression, epilepsy or type II diabetes
- medicines containing loperamide (anti-diarrheal)
- medicines of the NSAID class (non-steroidal agents for treatment of pain and/or inflammatory conditions, for example indomethacin).

Pregnancy and breastfeeding

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

Driving and using machines

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

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 standard initial dosage is usually 120 microgram, sublingually before bedtime. If required, the doctor may increase the dosage up to 240 microgram sublingually before bedtime.

Do not exceed the recommended dose.

Instructions for use
The medicine is intended for sublingual administration. Place it under the tongue, where it will completely dissolve with no need for water.

Do not take more than one prescribed dose in 24 hours.

If you have accidentally taken an overdose or if a child has accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the medicine package with you.
If you forgot to take the medicine at the scheduled time, never take two doses together! If you forgot to take the medicine, consult the doctor or pharmacist.

Adhere to the treatment as recommended by the 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 Melt** 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 this medicine and consult your doctor immediately if you experience:

- a very strong or persistent headache, abdominal pain, confusion, unexplained weight gain, nausea, vomiting, dizziness, sensation of general discomfort, memory impairment, sensation of lightheadedness, vertigo or falling.

- allergic reactions including itching, skin rash, swelling of the face, lips or mouth, difficulties breathing, wheezing, tension in the chest or cough.

Low sodium levels in your blood may cause convulsions. This may occur when you drink a large quantity of fluids during treatment with the medicine.

Additional side effects:

Common side effects (occur in 1-10 in 100 users)

Adults:

- increase in blood pressure
- diarrhea, constipation
- urinary symptoms
- tiredness
- swelling due to fluid accumulation

Uncommon side effects (occur in 1-10 in 1,000 users)

Adults:

- sleeping problems, 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:

- aggressiveness
- emotional instability
- diarrhea
- urinary symptoms

- swelling due to fluid accumulation
- tiredness

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

Adults:

- allergic skin reactions

Children and adolescents:

- anxiety symptoms
- nightmares
- mood changes
- sleepiness
- high blood pressure
- irritability

Side effects which their frequency cannot be estimated from the available information:

Adults:

- anaphylactic reactions (severe allergic reactions)
- convulsions
- coma

Children and adolescents:

- anaphylactic reactions (severe allergic reactions)
- abnormal behavior
- emotional disorders
- depression
- hallucinations
- insomnia
- concentration disorders
- increased restlessness and motion
- convulsions
- nose bleeds
- 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.

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting side effects following drug treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears 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 light and moisture.

6. Additional information

In addition to the active ingredients, this medicine also contains:

gelatin, mannitol, citric acid (anhydrous)

What the medicine looks like and contents of the pack:

Minirin Melt 120 mcg – a white, round tablet with two drops embossed on one side of the tablet.

Minirin Melt 60 mcg – a white, round tablet with one drop embossed on one side of the tablet.

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 GmbH, Kiel, Germany

Revised in September 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health’s National Drug Registry:

Minirin Melt 60 mcg 137 22 31462

Minirin Melt 120 mcg 137 23 31463