

Oral Lyophilisate for sublingual
Desmopressin Acetate 60mcg and 120mcg

Read the entire leaflet carefully before using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- 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 nurse. This includes any possible side effects not listed in the leaflet

What is in this leaflet:

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What MINIRIN[®] is used for

MINIRIN[®] is provided as oral lyophilisate in sublingual tablet.

It is used to treat:

- i. Central diabetes insipidus.
- ii. Primary nocturnal enuresis (from 5 years of age) when the enuresis alarm has not had the desired effect in patients with normal ability to concentrate urine.
- iii. Symptomatic treatment of nocturia in adults, associated with nocturnal polyuria, i.e. nocturnal urine production exceeding bladder capacity.

How MINIRIN[®] works

MINIRIN[®] contains active ingredient desmopressin (free base), as desmopressin acetate. Desmopressin is a structural analogue of the natural hormone arginine vasopressin. It provides an antidiuretic effect, lasting in most patients for 8-12 hours.

Before you use MINIRIN[®]

When you must not use it

Do not use MINIRIN[®] if you are:

- Habitual or psychogenic polydipsia (urine production exceeding 40 ml/kg/24 hours);
- Known or suspected cardiac insufficiency and other conditions that require treatment with diuretics;
- Moderate and severe renal insufficiency (creatinine clearance below 50 ml/min);
- Syndrome of inappropriate ADH secretion (SIADH);
- Known hyponatraemia;
- Hypersensitivity to the active substances or to any of the excipients (contain fish gelatin).

Before you start to use it

Before starting treatment with MINIRIN[®], you should check with your doctor.

In patients with urgency/urge incontinence, organic causes for increased micturition frequency or nocturia (e.g. benign prostate hyperplasia, urinary tract infection, and bladder stone/tumor), excessive thirst and poorly adjusted diabetes mellitus, the specific cause should be treated primarily.

At treatment of primary nocturnal enuresis and nocturia, fluid intake

should be limited to the least possible during the period of 1 hour before evening dose until at least 8 hours after administration. Treatment without concomitant reduction in fluid intake may lead to water retention and/or hyponatraemia (headache, nausea/vomiting, weight gain and in serious cases convulsions).

All patients and, when applicable, their guardians should be carefully instructed to adhere to the fluid restrictions.

Precautions to avoid hyponatraemia including careful attention to fluid restriction and more frequent monitoring of serum sodium must be taken at:

- concomitant treatment with drugs known to induce syndrome with disturbed ADH secretion (SIADH), e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRI), chlorpromazine and carbamazepine,
- concomitant treatment with NSAIDs.

Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Medicines that are known to induce disturbed Antidiuretic hormone secretion, e.g. tricyclic antidepressants, SSRI, chlorpromazine and carbamazepine as well as some antidiabetics of the sulfonylurea group, especially chlorpropamide, may cause an additive antidiuretic effect with an increased risk of fluid retention.

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NSAID preparations may induce water retention/hyponatraemia.

Concomitant treatment with loperamide may result in a three-fold increase in desmopressin plasma concentration, which may lead to an increased risk of water retention and/or hyponatraemia. Other drugs slowing intestinal transport might have the same effect. However, this has not been investigated.

Concomitant treatment with dimeticone may result in a decreased absorption of desmopressin.

It is unlikely that desmopressin interacts with pharmaceuticals affecting liver metabolism, since desmopressin has not been shown to undergo any significant liver metabolism in in vitro studies with human microsomes. However, no formal interaction studies in vivo have been carried out.

Concomitant food intake has not been investigated with MINIRIN[®] Oral Lyophilisate. A standardized meal with 27% fat taken together with or 1.5 h prior to MINIRIN[®] tablet decreased the extent and rate of absorption of desmopressin by 40%. No significant effect was observed with respect to pharmacodynamics (urine production or osmolality). It cannot be excluded that some patients may have decreased antidiuretic effect at concomitant food intake.

How to use MINIRIN[®]

Always take MINIRIN[®] exactly as directed by your doctor. Check with your doctor if you are not sure.

MINIRIN[®] Oral Lyophilisate is placed under the tongue where it is dissolved without water.

How much to use

The dose of MINIRIN[®] Oral Lyophilisate is individually adapted. MINIRIN[®] Oral Lyophilisate 60 mcg is calculated to correspond to MINIRIN[®] tablet 0.1 mg, and 120 mcg corresponds to 0.2 mg. Food intake causes decreased absorption and by that also might influence the effect of desmopressin.

In the event of signs of water retention/hyponatraemia (headache, nausea/vomiting, weight gain, and in serious cases convulsions) the treatment should be temporarily interrupted until the patient has completely recovered.

Indication specific

Central diabetes insipidus:

A suitable initial dose for children and adults is 60 mcg 3 times daily, administered sublingually. The dosage regimen is then adjusted in accordance with the patient's response. Clinical experience has shown, that the daily dose varies between 120 mcg and 720 mcg sublingually. For most patients, the maintenance dose is 60 mcg to 120 mcg sublingually 3 times daily. In the event of signs of water retention/hyponatraemia treatment should be temporarily interrupted and the dose should be adjusted.

Primary nocturnal enuresis

A suitable initial dose is 120 mcg at bedtime, administered sublingually. The dose may be increased up to 240 mcg sublingually if the lower dose is not sufficiently effective. Fluid intake should be controlled cautiously. When patient experience any signs or symptoms of water retention and/or

hyponatraemia, the treatment should be discontinued until patient has completely recovered. When the treatment is resumed, strict control of fluid intake is essential.

Nocturia

Nocturnal polyuria is characterized by an increased nightly urine output

The recommended initial dose is 60 mcg at bedtime, administered sublingually. If this dose is not sufficiently effective after one week, the dose may be increased up to 120 mcg sublingually and subsequently 240 mcg sublingually by weekly dose escalations. Control intake of fluid to avoid water retention and/or hyponatraemia.

When patient experience any signs or symptoms of water retention and/or hyponatraemia, the treatment should be discontinued until patient has completely recovered. When the treatment is resumed, strict control of fluid intake is essential.

Special Populations

Paediatric Population: MINIRIN[®] Oral Lyophilisate is indicated in Central Diabetes Insipidus and Primary Nocturnal Enuresis. Dose recommendations are the same as in adults.

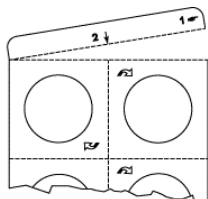
Elderly: Treatment of nocturia should not be initiated in patients >65 years.

The oral lyophilisates are brittle and could not be pressed through the foil since they may break. The oral lyophilisates should be taken out from the blisters by removing the aluminium cover

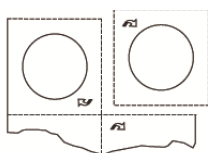
1. Remove the end tab completely starting from the

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corner where a hand symbol is printed.



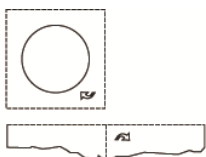
2. Tear off the blister unit along the vertical



3. Peel off the foil starting at the corner with the printed arrow. The product can then be removed from the pack



4. To access the next tablet, tear off the blister unit along the horizontal perforation.



When to use it

Use as directed by your doctor or pharmacist

How long to use it

Continue taking MINIRIN[®] for as long as your doctor recommends.

If you forget to use it

Do not take a double dose to make up for a forgotten dose. If you are not sure what to do, talk to your doctor or pharmacist.

If you use too much (overdose)

Please tell a nurse or doctor.

Overdosage leads to prolonged duration of action with an increased risk of fluid retention and hyponatraemia. Even normal doses may in combination with considerable fluid intake cause water intoxication.

The treatment of hyponatraemia should be individual.

While you are using it

Things you must do

Tell any other doctors or pharmacists who are treating you that you are using MINIRIN[®]. If you are about to start taking any new medicines, tell your doctor or pharmacist that you are using MINIRIN[®].

Things you must not do

Do not give MINIRIN[®] to anyone else, even if they have the same condition as you.

Do not use MINIRIN[®] to treat any other complaints unless your doctor has told you to.

Do not stop using MINIRIN[®] or lower the dosage, without checking with your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how MINIRIN[®] affects you.

Some people may experience drowsiness or dizziness. Make sure you know how you react to MINIRIN[®] before you drive a car, operate machinery or do anything else that could be dangerous if you

are dizzy or light-headed. If this occurs, do not drive.

Side Effects

Like all medicines, MINIRIN[®] can cause side effects, although not everybody gets them.

The most serious adverse reaction with desmopressin is hyponatraemia.

Very common side effect (≥1/10):
Headache

Common side effects (≥1/100, <1/10):

Hyponatraemia, Dizziness, Nausea, hypertension, abdominal pain, diarrhea, constipation, vomiting, bladder and urethral symptoms, oedema, fatigue.

Uncommon side effects (≥1/1000, <1/100):

Insomnia, Somnolence, Paraesthesia, Visual impairment, vertigo, palpitations, orthostatic hypotension, dyspnea, dyspepsia, flatulence, bloating and distension, sweating, pruritus, rash, urticarial, muscle spasms, myalgia, malaise, chest pain, Influenza like symptoms, weight increased, hepatic enzyme increased, hypokalaemia

Rare side effects (≥1/10 000, <1/1000):

Confusion state, Dermatitis allergic

In addition to above the following side effects were seen after MINIRIN[®] was marketed (frequency of these side effects is unknown):

Anaphylactic reaction, dehydration, hypernatraemia, convulsion, asthenia, coma.

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If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of MINIRIN[®]

Keep this medicine out of sight and reach of children.
Do not store above 30°C.
Store in the original package in order to protect from moisture and light.

Do not use MINIRIN[®] after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect the environment.

Product description

What it looks like

MINIRIN[®] Oral Lyophilisate for sublingual 60 mcg:
White, round, oral lyophilisate marked with a drop shaped figure on one side.

MINIRIN[®] Oral Lyophilisate for sublingual 120 mcg:
White, round, oral lyophilisate marked with two drop shaped figures on one side.

Aluminium/Aluminium blisters of 10 oral lyophilisates.
Pack sizes:
60 mcg: 30 oral lyophilisates.

120 mcg: 30 oral lyophilisates.
Not all pack sizes may be marketed.

Ingredients

MINIRIN[®] Oral Lyophilisate for sublingual 60 mcg:
One oral lyophilisate contains 60 mcg desmopressin (free base), as desmopressin acetate.

MINIRIN[®] Oral Lyophilisate for sublingual 120 mcg:
One oral lyophilisate contains 120 mcg desmopressin (free base), as desmopressin acetate.

Excipients: Gelatin (from fish), mannitol (E421) and citric acid, anhydrous (E330).

MAL number

60 mcg: [MAL17107075ACRZ](#)
120mcg: [MAL17107076ACRZ](#)

Manufacturer and Product Registration Holder

Marketing Authorisation Holder:
Ferring Sendirian Berhad
21-6, Block B, Jaya One,
No. 72-A, Jalan [Profesor Diraja Ungku Aziz](#),
46200 Petaling Jaya,
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Manufacturer:
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Frankland Road,
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10. Date of revision
[31-May-2023](#)

Serial Number
[NPRA \(R1/1\) 29052023/104](#)