MINIRIN® TABLET

Desmopressin Acetate (0.1mg, 0.2mg)

What is in this leaflet:

What MINIRIN® is used for

MINIRIN® is used to treat:

i. Central diabetes insipidus (disorder which leads to extreme thirst and large urine volumes).
ii. Bedwetting in children from 5 years of age with normal ability to concentrate urine.
iii. Nocturnal urgency (frequent urination during sleep) in adults.

How MINIRIN® works

Desmopressin acts as the natural hormone vasopressin and it regulates the kidneys ability to concentrate urine.

Before you use MINIRIN®

-When you must not use it

Do not use MINIRIN® if you have:

- Urine production exceeding 40 ml/kg/24 hours;
- Heart problems and other conditions that require treatment with diuretics (water pills);
- Moderate and severe kidney problems;
- Syndrome of inappropriate secretion of antidiuretics hormone (SIADH);
- Low blood sodium level;
- Hypersensitivity to Desmopressin or to any of the ingredients.

-Before you start to use it

Before starting treatment with MINIRIN®, you should check with your doctor, if you:
- are 65 years or older, have low blood sodium levels or high 24-hour urine production.
- have risk for increased pressure in the skull (e.g. systemic infections, fever, inflammation of the stomach and intestines).
- have enlarged prostate.
- have urinary tract infection.
- have bladder stone/growth.
- have excessive thirst.
- have poorly controlled diabetes.

When used for bedwetting and nocturnal urgency, the fluid intake to quench thirst must be limited to a minimum from 1 hour before until at least 8 hours after the intake of MINIRIN®.

MINIRIN® should be used with caution when the fluid balance is disturbed. Consult your doctor if you get disturbed fluid balance in connection with an acute illness.

-MINIRIN® tablets contain lactose

If you have intolerance to some sugars, contact your doctor before taking this medicine.

-Taking other medicines

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

The efficacy of MINIRIN® may be reinforced with an increased risk of abnormal accumulation of fluid in your body, if it is taken together with some medicines against:

- depression (tricyclic antidepressant, selective serotonin re-uptake inhibitors)
- psychosis (chlorpromazine)
- epilepsy (carbamazepine)
- diabetes (so called sulphonylurea e.g chlorpropamide
- diarrhoea (loperamide)
- pain and inflammation (so called NSAID)

The efficacy of MINIRIN® may decrease at concomitant treatment with some medicines such as:

- Dimeticone

-Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Experience from use during pregnancy is limited.
MINIRIN® enters milk from nursing mothers but is probably not affecting the nursed child. Anyway, desmopressin accumulation in breast milk upon repeated doses has not been studied.

How to use MINIRIN®

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

-How much to use

Indication specific

Central diabetes insipidus:

Initial dose is 0.1mg 3 times daily. The dosage regimen is then adjusted in accordance with the response. The daily dose varies between 0.2mg and 1.2mg. For most people, the maintenance dose is 0.1-0.2mg 3 times daily.

Bedwetting

Initial dose is 0.2mg at bedtime. The dose may be increased up to 0.4mg if the lower dose is not sufficiently effective. Fluid restriction must be enforced.

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Nocturnal urgency
Initial dose is 0.1mg at bedtime. If this dose is not sufficiently effective after one week, the dose may be increased up to 0.2mg and subsequently 0.4mg by weekly dose escalations. Fluid restriction must be enforced.

Treatment should not be initiated in the elderly (65 years of age and over). Should treatment of these elderly be considered, blood sodium should be measured before beginning of treatment and after 3 days of treatment.

Used in children:
MINIRIN® is used for treatment of central diabetes insipidus and bedwetting (see dosage for different treatment conditions above). Dosage is the same as for adults.

-When to use it
Use as directed by your doctor or pharmacist

-MINIRIN® with food and drink
Food intake may reduce the effect of MINIRIN®.

-How long to use it
Continue taking MNIRIN® for as long as your doctor recommends. If adequate effect is not achieved within 4 weeks following appropriate dose titration the treatment should be discontinued.

-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 low blood sodium level. Even normal doses may in combination with considerable fluid intake cause water intoxication. Refer to Section 'Side effects' for more information.

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
MINIRIN® has no or negligible effect on the ability to drive vehicles and use machine

Side Effects

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

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

Common side effects (≥1/100 people, <1/10 people):
- Low blood sodium level
- Dizziness
- Nausea and vomiting
- High blood pressure
- Abdominal pain
- Diarrhea
- Constipation
- Bladder and urethral symptoms
- Swelling
- Fatigue

Uncommon side effects (≥1/1000 people, <1/100 people):
- Visual impairment
- Strong rapid heartbeat
- Shortness of breath
- Chest pain
- Flu like symptoms
- Low blood potassium level

Rare side effects (≥1/10 000 people, <1/1000 people):
- Confusion state
- Skin Allergy

In addition to above the following side effects were seen after MINIRIN® was marketed (frequency of these side effects is unknown):
- Life-threatening allergic reaction
- Dehydration
- High blood sodium level
- Convulsion
- Abnormal weakness or lack of energy
- Coma

In the event of signs of water retention/low blood sodium level (headache, nausea/vomiting, weight gain, and in serious cases convulsions) the treatment should be temporarily interrupted until you have completely recovered. When the treatment is resumed strict fluid restriction is necessary.

Reporting of side effects
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

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Reaction Monitoring by visiting the website npra.gov.my
[Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of MINIRIN®®

-Storage
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.

-Disposal
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® 0.1 mg:
White, oval, convex tablet with a single score and marked "0.1" on one side.

MINIRIN® 0.2 mg:
White, round, convex tablet with a single score and marked "0.2" on one side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
The tablets are presented in a 30 ml plastic bottle with a desiccant capsule.
Pack sizes: 30 tablets

-Active ingredients
MINIRIN® 0.1 mg:
Each tablet contains desmopressin acetate 0.1 mg.

MINIRIN® 0.2 mg:
Each tablet contains desmopressin acetate 0.2 mg.

-Inactive ingredients
Lactose monohydrate, potato starch, povidone, magnesium stearate.

-MAL number
0.1mg: MAL19950096AZ
0.2mg: MAL19950097AZ

Product Registration Holder:
Ferring Sendirian Berhad
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