Minirin®
Tablets 0,1 and 0,2 mg

FERRING

48 18 60

Declaration
Tablets 0,1 mg. Each tablet contains desmopressin acetate 0,1 mg and excipients q.s.
Tablets 0,2 mg. Each tablet contains desmopressin acetate 0,2 mg and excipients q.s.

Properties
MINIRIN contains desmopressin, a structural analogue of the natural hormone arginine vasopressin. Two chemical changes have been made to the natural hormone, namely desamination of 1-cysteine and substitution of 8-L-arginine by 8-D-arginine. These structural changes result in a compound with significantly increased antidiuretic potency, very little activity on smooth muscle, hence the avoidance of undesirable pressor side effects. Oral administration of 0,1-0,2 mg desmopressin provides an antidiuretic effect lasting in most patients for 8-12 hours. Relative to intranasal administration the bioavailability is about 5 per cent.

Indications
- Central diabetes insipidus. The use of MINIRIN in patients with an established diagnosis will result in a reduction in urinary output with concomitant increase in urine osmolality and decrease in plasma osmolality.This will result in decreased urinary frequency and decreased nocturia.
- Primary nocturnal enuresis in children aged 5 years or more.

Contraindications
MINIRIN must NOT be used in cases of:
- habitual and psycogenic polydipsia
- cardiac insufficiency and other conditions requiring treatment with diuretic agents

Special precautions for use
Precautions to prevent fluid overload must be taken in:
- the very young and elderly patients
- conditions characterized by fluid and/or electrolyte imbalance
- patients at risk for increased intracranial pressure.

Pregnancy
Reproduction studies performed in rats and rabbits with doses more than 100 times the human dose have revealed no evidence of a harmful action of desmopressin on the foetus. One investigator has reported 3 cases of malformations in children to mothers suffering from diabetes insipidus and receiving desmopressin during pregnancy. However, several other published reports comprimising more than 120 cases show that women treated with desmopressin during pregnancy have given birth to normal children. Furthermore a review of a very large data set identifying 29 children who have been exposed to desmopressin during the full pregnancy shows no increase in the malformation rate in the children born.

Lactation
Results from analyses of milk from nursing mothers receiving high dose desmopressin (300 µg intranasally), indicate that the amounts of desmopressin that may be transferred to the child are considerably less than the amounts required to influence diuresis.

Undesirable effects
A few percent of treated patients can be expected to experience side effects such as headache, nausea and stomach pain.

Common (>1/100)	*General*: Headache *GI*: Stomach pain, nausea, *Upper respiratory*: Epistaxis

Treatment without concomitant restriction of water intake may lead to water retention with accompanying signs and symptoms (reduced serum sodium, weight gain, and, in serious cases, convulsions).

Interactions
Indomethacin may augment the magnitude but not the duration of the response to desmopressin.

Dosage and administration
Optimal dose of MINIRIN tablets is individually adjusted.
Central diabetes insipidus: A suitable initial dose for children and adults is 0,1 mg three times daily. The dose is then adjusted according to the response of the patient. According to clinical experience gained so far, the daily dose varies between 0,2 mg and 1,2 mg. For most patients, 0,1-0,2 mg three times daily is the optimal dose regimen.
Primary nocturnal enuresis: a suitable initial dose is 0,2 mg at bedtime. The dose may be increased up to 0,4 mg if the lower dose is not sufficiently effective. The need for continued treatment should be reassessed after 3 months by means of a period of at least 1 week without MINIRIN treatment. A restricted water intake must be observed, see also under Special warnings.

Overdose
Overdosage increases the risk of fluid retention and hyponatremia. Although the treatment of hyponatremia should be individualized, the following general recommendations can be given.
Asymptomatic hyponatremia is treated with discontinuation of desmopressin treatment and fluid restriction. Infusion of isotonic or hypertonic sodium chloride may be added in cases with symptoms. When the fluid retention is severe (convulsions and unconsciousness) treatment with furosemide should be added.

Special warnings
In case of treatment of enuresis the fluid intake must be limited to a minimum and only to satisfy thirst from 1 hour before until 8 hours after administration.
Substances which are known to release antidiuretic hormone, e.g. tricyclic antidepressants, chlorpromazine and carbamazepine, may cause an additive antidiuretic effect and increase the risk of water retention.

Note
Laboratory tests for monitoring the patient include urine volume and osmolality. In some cases plasma osmolality may be required.

Stability and storage
MINIRIN tablets should be stored at room temperature (maximum 25°C) and in a dry place (maximum 60 % relative humidity).
In areas where humidity and temperature is higher than the ones suggested, the bottles should be stored in a refrigerator. The top cap of the bottle should be firmly closed and the dessicator should be kept inside the bottle.

Legal category
Prescription only medicine.

Package quantities
0,1 mg: 30 tablets
0,2 mg: 30 tablets

Manufacturer
FERRING AB
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THIS IS A MEDICINE

- A MEDICINE IS A PRODUCT WHICH AFFECTS YOUR HEALTH, AND ITS CONSUMPTION CONTRARY TO INSTRUCTIONS IS DANGEROUS FOR YOU.
- STRICTLY FOLLOW THE DOCTOR'S PRESCRIPTION, THE METHOD OF USE AND THE INSTRUCTIONS OF THE PHARMACIST WHO SOLD THE MEDICINE.
- THE DOCTOR AND THE PHARMACIST ARE EXPERTS IN MEDICINE, ITS BENEFITS AND RISKS.
- DO NOT BY YOURSELF INTERRUPT THE PERIOD OR TREATMENT PRESCRIBED FOR YOU.
- DO NOT REPEAT THE SAME PRESCRIPTION WITHOUT CONSULTING YOUR DOCTOR.