Approved Patient Information Leaflet

SCHEDULING STATUS:

S3

PROPRIETARY NAME (and dosage form):

TORSINAT 2,5 mg tablets

TORSINAT 5 mg tablets

TORSINAT 10 mg tablets

COMPOSITION (WHAT THIS MEDICINE CONTAINS):

TORSINAT 2,5 mg: Each tablet contains 2.5 mg torasemide

TORSINAT 5 mg: Each tablet contains 5.0 mg torasemide

TORSINAT 10 mg: Each tablet contains 10.0 mg torasemide

INDICATIONS (WHAT THIS MEDICINE IS USED FOR):

Essential hypertension

Oedema of cardiac and hepatic origin

Pulmonary oedema due to acute cardiac insufficiency

INSTRUCTIONS BEFORE TAKING THIS MEDICINE:

CONTRA-INDICATIONS:

TORSINAT must not be used:

In renal failure with absence of urine production (anuria)

Hepatic precoma and coma

During pregnancy and lactation

In patients with known hypersensitivity to sulfonylureas

Hypovolaemia

Hyponatraemia, hypokalaemia

Severe disorders of micturition (e.g. prostate hypertrophy)

Due to the lack of clinical experience, torasemide should not be used in children of 12 years or younger

SPECIAL PRECAUTIONS:

Regular monitoring of the electrolyte balance, glucose, uric acid, creatinine and lipid levels is required with long-term torasemide treatment.

In patients with a tendancy to hyperuricaemia and gout, careful monitoring is required. An increase in blood glucose may occur, thus careful monitoring of the carbohydrate metabolism in patients with latent or manifest diabetes mellitus is recommended.

POTENTIAL EFFECTS ON ALERTNESS:

Alertness may be impaired (e.g. patient's ability to drive vehicles or to operate machinery). This applies particularly when beginning treatment, switching from another medicine or starting a new co-medication, and in conjuction with alcohol.

INTERACTIONS:

Simultaneous use with cardiac glycosides, may result in a potassium and / or magnesium deficiency which may increase the sensitivity of the cardiac muscle to digitalis.

There may be an increase in the kalidiuretic effect of mineralo and glucocorticosteroids and laxatives.

Potentiation of the effect of antihypertensive medicines may occur. Consecutive treatment or start of a new co-medication with an ACE-inhibitor may result in an excessive fall in blood pressure.

The action of anti-diabetic medicines may be reduced.

The effect of torasemide may be reduced by nonsteroidal anti–inflammatory agents.

The action of curare containing muscle relaxants and of theophylline can be potentiated.

The damaging effects of aminoglycocide antibiotics, cisplatin preparations and cephalosporins on the ear and kidney especially at high dose therapy may be potentiated by torasemide.

Arterial responsiveness to pressor agents e.g. adrenaline and noradrenaline may be decreased by torasemide. Toxicity may be increased occur in patients receiving high doses of salicylates.

During concomitant administration with cholestyramine, bioavailability and thus the effectiveness of torasemide may be reduced.

PREGNANCY AND LACTATION:

TORSINAT must not be used during pregnancy and lactation.

If you are taking this medicine on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advise.

If you are pregnant or breast feeding your baby while taking this medicine, please consult you doctor, pharmacist or other health care professional for advise.

DOSAGE AND DIRECTIONS FOR USE (HOW TO TAKE THIS MEDICINE):

ESSENTIAL HYPERTENSION:

Treatment is initiated with one tablet torasemide 2,5 mg per day. The usual maintenance dose is 2,5 mg per day. If this is not sufficiently effective, the dose can be doubled to 5,0 mg per day. Higher doses will not lead to a further reduction of blood pressure.

OEDEMA OF CARDIAC, HEPATIC AND RENAL ORIGIN:

Treatment is initiated with one tablet torasemide 5,0 mg per day. The usual maintenance dose is 5,0 mg per day. If this is not sufficiently effective, the dose can be increased up to 20,0 mg per day depending on the severity of the disease. In individual cases as much as 40 mg torasemide per day

has been administered. Oral torasemide may be taken with some liquid on an empty stomach or at any time in relation to a meal, as convenient.

Do not share medicines prescribed for you with others.

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Disturbances of water and electrolyte balance may occur, especially with limited salt intake, depending on the dosage and duration of treatment.

Marked diuresis, especially at the start of treatment and in elderly patients may result in signs of electrolyte and volume deficiency e.g. dizziness, feelings of weakness, headache, loss of appetite and cramps. As a result of haemoconcentration after marked diuresis, hypotension and confusional states may occur. Gastro-intestinal symptoms (nausea, vomiting, diarrhoea, constipation) may also occur. There may be an occurrence of thromboembolic complications and cardiac or cerebral ischaemia. These side effects are generally abolished by adjusting the dosage to the individual needs. Rarely, treatment with torasemide may cause a decrease in the corpuscular constituents of the blood (erythrocytes, leucocytes, platelets).

An increase in urine production in patients with urinary obstructions (e.g. prostate hypertrophy) can lead to urine retention resulting in distension of the bladder. During treatment with torasemide there may be an increase in blood urea and creatinine, even in clinically healthy patients or in the presence of damaged kidneys.

Reduced potassium levels may occur in the blood, especially in patients consuming a low potassium diet or in patients with vomiting, diarrhoea and excessive use of laxatives and in chronic disorders of liver function.

Allergic skin reactions e.g. pruritus and exanthema or photosensitization have been reported in isolated cases. Rarely, dryness of the mouth and paraesthesia in the limbs and visual disturbances have been reported.

Increases in Gamma-GT, alteration in the blood glucose and lipid metabolism and a raise in the uric acid level may occur.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE INSTRUCTIONS (STORAGE AND DISPOSAL INFORMATION):

Store at or below 25 °C.

Keep all medicines out of the reach of children.

PRESENTATION:

Aluminim/Aluminium or clolourless PVC/PVDC/Aluminium blister packs containing 30 tablets.

IDENTIFICATION OF THE MEDICINE:

TORSINAT 2,5 mg: White to off-white, round tablet without break notch

TORSINAT 5 mg: White to off-white, round tablet with break notch

TORSINAT 10 mg: White to off-white, round tablet with cross break notch

REGISTRATION NUMBERS:

TORSINAT 2,5 mg: A39/18.1/0192

TORSINAT 5 mg: A39/18.1/0193

TORSINAT 10 mg: A39/18.1/0194

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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