

PATIENT INFORMATION LEAFLET

TORSEMIDE TABLETS 10 mg (TORSINEX-10)



Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider><or><pharmacist>.

Prescription only medicine

In this leaflet:

- a) What Torsinex is and what it is used for
- b) Before you take Torsinex
- c) How to take Torsinex
- d) Possible side effects
- e) How to store Torsinex
- f) Further information

a. What Torsinex is and what it is used for

Torsemide is a loop diuretic. However, at low doses its Pharmacodynamic profile resembles that of the thiazide class regarding the level and duration of diuresis. At higher doses, Torsemide induces a brisk diuresis in a dose dependent manner with a high ceiling of effect.

Torsinex contains a medicine called Torsemide. This belongs to a group of medicines called 'diuretics' or 'water tablets'.

- Torsinex tablets are used to treat high blood pressure (hypertension).
- Torsinex tablets are used to treat swelling caused by too much water in the body (oedema).

The tablets work by making you pass more water (urine).

b. Before you take Torsinex

Do not take Torsinex if you are allergic (hypersensitive) to:

- Torsemide or any of the other ingredients of Torsinex
- Similar medicines called 'sulphonylureas'. These are used to treat diabetes (high blood sugar).
- These medicines include chlorpropamide, glibenclamide, Glipizide and tolbutamide.

Do not take Torsinex if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before taking Torsinex.

Do not take Torsinex if:

- You have kidney problems (renal failure).
- You have kidney problems that have been caused by medicines.
- You have difficulty passing water (urinating).
- You have liver problems.
- You have a low volume of blood (hypovolaemia).
- You have low blood pressure (hypotension).
- You have heart beat problems (cardiac arrhythmia).
- You have gout or high levels of uric acid in your blood.

- You are taking an antibiotic called an ‘aminoglycoside’ or ‘cephalosporin’ (for an infection). These medicines include streptomycin, gentamycin, cephalexin and ceftriaxone. See the section on ‘Taking other medicines’.
- You are pregnant or breast-feeding a baby. See the section on ‘Pregnancy and breast-feeding’.
- You are aged 12 years or younger.

Do not take Torsinex if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before taking Torsinex.

Take special care with Torsinex

Check with your doctor or pharmacist before taking Torsinex if:

- You have low levels of potassium or sodium in your blood (shown in blood tests).
- You have diabetes (diabetes mellitus).

If any of these apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Torsinex.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

This is because Torsinex can affect the way some other medicines work.

Also some other medicines can affect the way Torsinex works.

Do not take Torsinex if you are already taking an antibiotic called an ‘aminoglycoside’ or ‘cephalosporin’ (for an infection). These medicines include streptomycin, gentamycin, cephalexin and ceftriaxone. If this applies to you, ask your doctor or pharmacist for advice.

It is particularly important to **tell your doctor or pharmacist** if you are taking any of the following medicines:

- Other medicines to treat high blood pressure.
- Medicines called ‘ACE inhibitors’ (used to treat heart disease).
- Medicines like digoxin or digoxin (used to treat heart disease).
- Adrenaline (also called epinephrine) or noradrenaline (also called norepinephrine). These are used to treat low blood pressure.
- Cholestyramine, or other ‘ion exchange resins’ (used to treat high levels of cholesterol in your blood)
- High doses of medicines called ‘salicylates’, such as aspirin.
- Medicines called ‘non-steroidal anti-inflammatory drugs’ (NSAIDs). These include indomethacin and ibuprofen.
- Laxatives.
- Steroid medicines, such as hydrocortisone, prednisolone and dexamethasone.
- Medicines to relax your muscles (muscle relaxants).
- Cisplatin (used to treat cancer).
- Lithium (used to treat mental health problems).
- Probenecid (used to treat gout).
- Theophylline (used to treat asthma).

Pregnancy and breast-feeding

Do not take Torsinex if you are pregnant, might become pregnant or are breast-feeding. This is because it is not known if Torsinex will affect your baby.

Driving and using machines

You may feel dizzy while taking Torsinex. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Torsinex

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have intolerance to some sugars), talk to your doctor before taking this medicine.

c. How to take Torsinex

Always take Torsinex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

High blood pressure

- The usual dose for adults and elderly people is between 2.5 mg and 5 mg once a day.

Water retention (oedema)

- The usual dose for adults and elderly people is 5 mg once a day.
- Your doctor may increase the dose to 20 mg a day if needed.

If you take more Torsinex than you should

- If you take more Torsinex than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.
- If you take too many tablets, you may pass a lot of urine, become sleepy, or feel confused, faint or dizzy. You may also have stomach upset.

If you forget to take Torsinex

- If you forget to take a dose, take it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If someone else takes your Torsinex tablets by mistake, they should talk to a doctor or go to a hospital straight away. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

d. Possible side effects

Like all medicines, Torsinex can cause side effects, although not everyone will get them.

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories:

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very rare ($< 1/10,000$)

Not known (cannot be estimated from available data)

The following undesirable effects were observed whereas the frequency of undesirable effect is not known:

See your doctor as soon as possible if you get the following side effects:

Blood and lymphatic system disorders

Frequency not known: Thrombocytopenia, Leukopenia, Anaemia

Immune system disorders

Very rare: Allergic skin reactions (e.g. Pruritus, Exanthema), Photosensitivity reaction

Frequency not known: Serious skin reactions (e.g. Stevens-Johnson syndrome, Toxic epidermal necrolysis)

Metabolism and nutrition disorders

Common: Metabolic alkalosis, Fluid and electrolyte imbalance (e.g. Hypovolaemia, Hyponatraemia)

Nervous system disorders

Common: Headache, Dizziness

Frequency not known: Cerebral ischemia, Parosmia, Confusional state

Eye disorders

Frequency not known: Visual impairment

Ear and labyrinth disorders

Frequency not known: Tinnitus, Deafness

Cardiac disorders

Frequency not known: Acute myocardial infarction, myocardial ischemia, Angina pectoris, Syncope, Hypotension

Vascular disorders

Frequency not known: Embolism

Gastrointestinal disorders

Common: Gastrointestinal disorder (e.g. Loss of appetite, abdominal pain upper, Nausea, Vomiting, Diarrhoea, Constipation)

Frequency not known: Dry mouth, Pancreatitis

Hepatobiliary disorders

Uncommon: Hepatic enzyme increased (e.g. Gamma-glutamyl transferase increased)

Skin and subcutaneous tissue disorders

Very rare: Allergic skin reactions (e.g. Pruritus, Exanthema), Photosensitivity reaction

Frequency not known: Serious skin reactions (e.g. Stevens-Johnson syndrome, Toxic epidermal necrolysis)

Musculoskeletal and connective tissue disorders

Common: Muscle spasms

Renal and urinary disorders

Uncommon: Urinary retention, Bladder dilatation

Rare: Blood urea increased, Blood creatinine increased

General disorders and administration site conditions

Common: Fatigue, Asthenia

Investigations

Uncommon: Blood uric acid increased, Blood glucose increased, Lipids increased (e.g. Blood triglycerides increased, Blood cholesterol increased)

Other possible side effects:

Blood

- An increase in the levels of certain substances in your blood, including sugar, uric acid and fats (lipids). Your doctor may do blood tests from time to time to make sure that Torsinex is working safely.

Stomach and gut

- Stomach upset.
- Inflammation of the pancreas causing pain in the stomach (pancreatitis).
- Changes in how your liver is working (shown by blood tests).

Skin

- Skin rashes and itchy skin.
- Skin being more sensitive to the sun (photo-sensitivity).

Eyes and ears

- Blurred eyesight.
- Ringing in the ears (tinnitus) and loss of hearing.

Other

- Feeling numb or tingling in the legs or arms.
- Dry mouth.
- Some people may have difficulty passing water (urinating).

e. How to store Torsinex

Store below 30°C. Keep out of the reach and sight of children. Do not use Torsinex after the expiry date printed on the pack.

Do not throw away any leftover tablets. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

f. Further information

What Torsinex contains

The active substance is Torsemide

The other ingredients are: Lactose, Microcrystalline cellulose, Povidone, Crospovidone, Colloidal anhydrous silica, Magnesium stearate, Talc

What Torsinex looks like and contents of the pack

White, circular, flat, bevel edged uncoated tablets with a break-line one surface.

Break line is to facilitate breaking for ease of swallowing and not for dividing into equal doses.

Blister pack of 10's

Name and full physical address of Marketing Authorization Holder and Manufacturing site

Marketing Authorization Holder

MICRO LABS LIMITED

31, Race course road

Bangalore-560001

INDIA

Manufacturer

MICRO LABS LIMITED

No. 92, Sipcot Industrial Complex

Hosur -635 126 (TN)

INDIA

For any information about this medicinal product, please contact the <local representative of the> supplier:

Country: Rwanda

M/s.Wessex

Pharmaceuticals (Rwanda) Ltd

C/o.Phillips Pharmaceuticals (Rwanda) Ltd

Shop No: Gf68, Kigali Modern City Market Commercial Street

Kigali, Rwanda

This leaflet was last approved in

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