

Package leaflet: Information for the patient

Torsemide 5 mg Tablets

Torsemide 10 mg Tablets

Torsemide

Read all of this leaflet carefully before you start taking 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 pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their sign of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What Torsemide is and what it is used for
2. What you need to know before you take Torsemide
3. How to take Torsemide
4. Possible side effects
5. How to store Torsemide
6. Contents of the pack and other information

1. What Torsemide is and what it is used for

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

Torsemide 5 mg and 10 mg 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).

2. What you need to know before you take Torsemide

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

- Torsemide or any of the other ingredients of torsemide (see section 6: Contents of the pack and other information).
- Similar medicines called 'sulphonylureas'. These are used to treat diabetes (high blood sugar). These medicines include chlorpropamide, glibenclamide, glipizide and tolbutamide.

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

Do not take torsemide if:

- You have kidney problems (renal failure)
- You have kidney problems that have been caused by medicines.
- 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 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'.

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

Take special care with torasemide

Check with your doctor or pharmacist before taking torasemide if:

- You have low levels of potassium or sodium in your blood (shown in blood tests).
- You have difficulty with micturition (passing urine) including prostatic hypertrophy.
- 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 torasemide.

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 torasemide can affect the way some other medicines work. Also some other medicines can affect the way torasemide works.

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

Driving and using machines

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

Important information about some of the ingredients of torasemide

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Torasemide

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

Oedema

- The usual dose is 5 mg once daily. Your doctor may increase the dose to 20 mg a day if needed.

Torasemide Tablets cannot be divided for dosing. Another strength or formulation of torasemide should be used when doses are not achievable with Torasemide Tablets.

If you take more Torasemide than you should

- If you take more torasemide 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 Torasemide

- 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 torasemide 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.

4. Possible side effects

Like all medicines, torasemide 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 ($\geq 1/1,000$ to $< 1/100$)

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 ischaemia, Parenthesia, 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 ischaemia, Angina pectoris, Syncope, Hypertension

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-glutamyltransferase 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 dilation

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 torasemide is working safely.

Stomach and gout

- 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).

If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: HPRA

Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Torasemide

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or container after "EXP." The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Torasemide tablet contains

The active substance is torasemide.

- Torasemide 5 mg tablets (each tablet contains 5 mg of torasemide).
Torasemide 10 mg tablets (each tablet contains 10 mg of torasemide).
- The other ingredients are lactose monohydrate, pregelatinised starch, colloidal anhydrous silica, magnesium stearate.

What Torasemide tablets look like and contents of the pack

PVC/PVDC Clear Alu-blister pack, containing 10, 14, 28 and 30 tablets

PVC Clear Alu-Blister pack, containing 10, 14, 28 and 30 tablets

Not all pack sizes may be marketed.

Torasemide 5 mg tablets

White to off white, round tablets, with the imprint "T 5" and scoreline on one side and plain on other side.

Torasemide 10 mg tablets

White to off white, round tablets, with the imprint "T 10" and scoreline on one side and plain on other side.

Marketing Authorisation Holder

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