

PACKAGE LEAFLET: INFORMATION FOR THE USER

TOREM

5mg Tablets, 10mg Tablets

TORASEMIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 only • Do not pass it on to others • It may harm them, even if their signs 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 •

What is in this leaflet?

1. What TOREM is and what it is used for
2. Before you take TOREM
3. How to take TOREM
4. Possible side effects
5. How to store TOREM

1. WHAT TOREM IS AND WHAT IS IT USED FOR

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

- TOREM 5 mg tablets are used to treat high blood pressure (hypertension).
- TOREM 5 mg and 10 mg tablets are used to treat swelling caused by too much water in the body (oedema).

2. BEFORE YOU TAKE TOREM

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

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

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

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

Take special care with TOREM

Check with your doctor or pharmacist before taking TOREM 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 TOREM.

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 TOREM can affect the way some other medicines work.

Also some other medicines can affect the way TOREM works.

Do not take TOREM 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 'ionexchange resins' (used to treat high levels of cholesterol in your blood).
- High doses of medicines called 'salicylates', such as aspirin.
- Medicines called 'non-steroidal antiinflammatory 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 TOREM if you are pregnant, might become pregnant or are breast-feeding. This is because it is not known if TOREM will affect your baby.

Driving and using machines

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

Important information about some of the ingredients of TOREM

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 an intolerance to some sugars), talk to your doctor before taking this medicine.

3. HOW TO TAKE TOREM

Always take TOREM 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 TOREM than you should

- If you take more TOREM 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 TOREM

- 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 TOREM 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, TOREM 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: Thrombozytopenia, 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, Parenthesis, 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, 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-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 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 TOREM 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).

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.

By reporting side effects you can help provide more information on the safety of this medicine

5. HOW TO STORE TOREM

- TOREM tablets do not need special storage conditions.
- Keep out of the reach and sight of children.
- Do not use TOREM after the expiry date printed on the pack.
- Do not throw away any left over tablets. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.