

Package leaflet: Information for the patient

**Torasemide 5 mg Tablets
Torasemide 10 mg Tablets**

[To be completed nationally]

torasemide

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. See section 4.

What is in this leaflet

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

1. What Torasemide Tablets are and what they are used for

Torasemide is a type of medicine called a diuretic, which increases the amount of water (urine) passed. It is used when your body is retaining too much water (oedema) due to heart failure. You will be given a dose of torasemide that will make you pass more water.

2. What you need to know before you take Torasemide Tablets

Do not take Torasemide Tablets:

- if you are allergic to torasemide or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to similar medicines called sulphonylureas (eg. chlorpromamide, glibenclamide, glipizide)
- if you have severe kidney problems where there is no production or passing of urine
- if you have a liver disease that causes you to become unconscious, confused and drowsy (precomatose)
- if you have been told you have very low blood pressure

- if you are breast-feeding

Warnings and precautions

Talk to your doctor or pharmacist before taking Torasemide Tablets

- if you have been told by your doctor that you have low blood potassium or sodium levels or a low volume of blood in your body. These conditions need to be corrected before you can start taking this medicine.
- if you suffer from gout or diabetes. Your doctor will need to monitor you carefully while you are taking this medicine.
- if you have any kidney problems or problems passing urine e.g. Benign Prostatic Hyperplasia – enlarged prostate. This medicine may not be suitable for you.
- if you have been told that you suffer from irregular heart beat. This medicine may not be suitable for you.
- if you are under 12 years old. There is not enough experience of use of this medicine in young children.
- if you have a condition which causes too much acid or base in your blood or tissues.

If you are going to be taking this medicine for a long period of time you will need to be monitored more closely and your doctor will carry out extra blood tests.

Other medicines and Torasemide Tablets

Some medicines may not work well together. One medicine may stop another from working properly or the effects of some medicines taken together may make you feel unwell.

Talk to your doctor before taking Torasemide Tablets if you are taking any of the following medicines. Your doctor needs to know if you are taking any of these medicines, so that the right dose of Torasemide Tablets can be given to you. You may also need to be monitored more closely and blood tests taken.

- certain types of antibiotics e.g. aminoglycosides (such as gentamicin, streptomycin and neomycin) and cephalosporins (such as cefuroxime, cefalexin and ceftazidime) – used to treat infections
- digoxin or digitoxin – used to treat heart failure
- medicines used to treat high blood pressure, especially ACE-inhibitors e.g. enalapril. The starting dose of the ACE-inhibitor or Torasemide may have to be reduced when these medicines are given together.
- medicines used to treat low blood pressure e.g. noradrenaline or adrenaline
- laxatives
- steroids – used to treat inflammation
- non-steroidal anti-inflammatory medicines – e.g. ibuprofen, naproxen, aspirin, indomethacin
- theophylline – used to treat asthma
- anti-diabetic medicines
- muscle relaxants (which contain curare - used in general anaesthesia)
- probenecid – a medicine used to treat gout
- cholestyramine - used to lower blood fats

- cisplatin – used to treat cancer
- lithium – used to treat depression

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Torasemide Tablets with food, drink and alcohol

Drinking alcohol while taking this medicine may make you dizzy or drowsy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine if you are breast-feeding.

Driving and using machines

This medicine may make you feel dizzy or drowsy. This is more likely to happen when you first start taking this medicine, your doctor increases your dose or if you drink alcohol.

Do not drive and do not use any tools or machines if you feel dizzy or drowsy.

Torasemide Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Torasemide Tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Torasemide Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be taken in the morning and swallowed whole with a small glass of water. Do not chew the tablets.

The tablet can be divided into equal doses.

Use in adults and elderly

The usual dose is 5 mg daily, but your doctor may prescribe a higher dose. The maximum dose is 20 mg a day.

Use in children

There is no experience of treatment of children with torasemide.

Use in patients with liver and kidney disease

There is limited information on dosage adjustments in patients with liver or kidney diseases. Your doctor will monitor you closely and adjust your dose as necessary.

If you take more Torasemide Tablets than you should

If you or someone else takes too many Torasemide Tablets you may experience the following symptoms:

- pass a lot of water (urine)
- sleepiness
- confusion
- weakness
- dizziness
- upset stomach.

You should contact your doctor, pharmacist or hospital emergency department immediately. Always take any tablets left over with you and also the box, as this will allow easier identification of the tablets.

If you forget to take Torasemide Tablets

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose.

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following:

You may need medical attention, have your medicine stopped or the dose altered.

Very rare: may affect up to 1 in 10,000 people

- severe skin rash

Not known: frequency cannot be estimated from the available data

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- reduction in number of white blood cells which makes infections more likely
- reduction in blood platelets, which increases risk of bleeding or bruising
- complications due to blood clots and disturbances in blood circulation (including insufficient blood supply of heart or brain). This may cause chest pain (angina

pectoris), changes in the heart beat, other problems with your heart (e.g. heart attack) or fainting (syncope). These effects may happen if your medicine makes you pass too much water (urine) which leads to a thickening of the blood. This is more likely if you are elderly or when you first start taking this medicine.

- disturbances of water and electrolyte balance (especially with markedly limited salt intake) as well as low levels of potassium and sodium (especially in cases of low potassium diet, vomiting, diarrhoea/excessive use of laxative, or hepatic failure). Low level of potassium in your blood which can cause muscle weakness, twitching or abnormal heart rhythm, or low level of sodium in your blood which can cause tiredness, confusion, feeling or being sick, cramps, fits and coma. These effects may happen if your medicine makes you pass too much water (urine). This is more likely if you are elderly or when you first start taking this medicine
- low blood pressure (dizziness when getting up from a sitting or lying position)
- inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis)
- loss of hearing

Tell your doctor if you experience any of the following and they are bothersome or do not improve:

You may need medical attention only if they continue or become bothersome. There is usually no need for your medicine to be stopped.

Common: may affect up to 1 in 10 people

- headache, dizziness, tiredness, weakness
- stomach upset (e.g. loss of appetite, stomach pain, vomiting), diarrhoea, constipation

Rare: may affect up to 1 in 1,000 people

- numbness or tingling in the legs or arms

Very rare: may affect up to 1 in 10,000 people

- allergic reactions such as itching, skin rash or increased sensitivity of the skin to light

Not known: frequency cannot be estimated from the available data

- raised levels of sugar, uric acid, and lipids (fats) in your blood. Your doctor may wish to test your blood.
- aggravation of acid-base imbalance which may cause headache, lethargy and muscle cramps
- visual disturbances e.g. blurred eyesight
- ringing or buzzing in the ears
- changes in some liver enzymes
- difficulty in passing water
- raised serum urea and creatinine
- dry mouth

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Torasemide Tablets

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 after EXP.
The expiry date refers to the last day of that month.
Do not store above 30°C.

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 to protect the environment.

6. Contents of the pack and other information

What Torasemide Tablets contain

- The active substance is torasemide. Each tablet contains either 5 mg or 10 mg of torasemide.
- The other ingredients are lactose monohydrate, maize starch, sodium starch glycolate Type A, silica colloidal anhydrous and magnesium stearate.

What Torasemide Tablets look like and contents of the pack

Torasemide 5 mg Tablets are white to almost white, round, biconvex tablets with a score line on one side and marked with '915' on the other.

Torasemide 10 mg Tablets are white to almost white, round, biconvex tablets with a score line on one side and marked with '916' on the other.

Pack sizes: Blister packs of 10, 14, 28, 30, 50, 100 or 112 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in {MM/YYYY}.

[To be completed nationally]