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Torasemide 5 mg Tablets Torasemide 10 mg Tablets torasemide

Package leaflet: Information for the patient

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 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 (coma hepaticum) until improvement or removal of this condition
- if you have very low blood pressure (hypotension)
- if you have a low volume of blood (hypovolaemia)
- if you have low potassium or sodium levels in the blood (hyponatraemia, hypokalaemia)
- if you have severe urinary flow disorders caused e.g. by an enlarged prostate gland
- if you are breast-feeding
- if you have gout
- if you have irregular heartbeat
- if you are taking certain types of antibiotics (aminoglycosides or cephalosporins)
- if you have impaired kidney function due to medicines which cause kidney damage.

Warnings and precautions

Talk to your doctor or pharmacist before taking Torasemide Tablets:

- if you have abnormal changes in the amount of acid and base in the body
- if you have abnormal changes in the blood count (e.g. thrombocytopenia or anaemia in patients without renal insufficiency)
- if you suffer from abnormal urine flow, this must be corrected prior treatment start with Torasemide Tablets.

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, particularly if you use other medicines, if you have diabetes, or are suffering from arrhythmias.

Children

Torasemide Tablets is not recommended for children below the age of 12 years. There is not enough experience of use of this medicine in children.

Other medicines and Torasemide Tablets

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

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 kanamycin, gentamicin, tobramycin, 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
- medicines containing cortisone
- non-steroidal anti-inflammatory medicines e.g. ibuprofen, naproxen, acetylsalicylic acid, 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

- coumarin derivatives, e.g. phenprocoumon – used to thin the blood.

Torasemide Tablets with 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.

Only take Torasemide Tablets during pregnancy if your doctor indicates that it is absolutely necessary. The lowest possible dose should be used in this case.

Do not take this medicine if you are breast-feeding as a risk for the newborn/child can not be excluded.

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, changes the medicine or initiates additional medicine or if you drink alcohol.

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

Effects in the case of misuse for doping purposes

Torasemide Tablets use can lead to positive results in doping tests. Torasemide Tablets use as a doping agent can be harmful to health.

Torasemide Tablets contains 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 contains 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.

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

Your doctor will monitor you closely and adjust your dose as necessary.

Method and duration of administration

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.

Your doctor will decide on the duration of treatment.

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
- hypotension
- circulatory collapse
- 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 take too little or forget to take [Torasemide Tablets, the effect will be weakened. This can lead to a worsening of the symptoms, e.g. weight gain, increased water retention in the tissues, etc.

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 stop taking Torasemide Tablets

In case of interruption or premature termination, a worsening of the symptoms is also to be expected. You should therefore never interrupt or prematurely stop taking Torasemide Tablets without consulting your doctor.

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.

Common: may affect up to 1 in 10 people

- disturbances of water and electrolyte balance such as reduced blood volume as well as low levels of potassium (especially in cases of low potassium diet, vomiting, diarrhoea/excessive use of laxative, or hepatic dysfunction) and of sodium in your blood. These conditions may cause headache, dizziness, hypotension, weakness, drowsiness, confusional states, loss of appetite and cramps, 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.
- aggravation of acid-base imbalance which may cause headache, lethargy and muscle cramps

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

- severe skin reactions, such as skin rash with redness and blister formation (e.g. Stevens Johnson syndrome and toxic epidermal necrolysis)
- reduction in red blood cells (can make the skin pale and cause weakness or breathlessness), reduction in white blood cells (makes infections more likely), reduction in

blood platelets, (increases the risk of bleeding or bruising)

- complications due to thickening of the blood may lead to low blood pressure and disturbances in blood circulation (including insufficient blood supply of heart or brain). This may cause chest pain (angina pectoris), changes in the heartbeat, 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.
- complications due to blood clots caused by thickening of the blood
- 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, particularly at the beginning of treatment
- muscle cramps, particularly at the beginning of therapy
- stomach upset (e.g. loss of appetite, stomach pain, feeling sick, vomiting), diarrhoea, constipation, particularly at the beginning of treatment
- raised levels of sugar, uric acid, and lipids (fats) in your blood. Your doctor may wish to test your blood.
- changes in some liver enzymes.

Uncommon: may affect up to 1 in 100 people

- numbness or tingling in the legs or arms
- dry mouth
- difficulty in passing water which can lead to urinary retention
- raised serum urea and creatinine.

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
- low blood pressure (dizziness when getting up from a sitting or lying position)
- visual disturbances e.g. blurred eyesight
- ringing or buzzing in the ears.

Not known: frequency cannot be estimated from the available data

- insufficient blood flow to the brain, confusion.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 25°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 looks 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 side.

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 side.

Pack sizes: Blister packs of 10, 14, 28, 30, 50, 100 or 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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