

Package leaflet: Information for the patient

Torasemid Zentiva 2.5 mg tablet
Torasemid Zentiva 5 mg tablet
Torasemid Zentiva 10 mg tablet
Torasemid Zentiva 20 mg tablet

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 <[Invented name]> is and what it is used for
2. What you need to know before you take <[Invented name]>
3. How to take <[Invented name]>
4. Possible side effects
5. How to store <[Invented name]>
6. Contents of the pack and other information

1. What <[Invented name]> is and what it is used for

<[Invented name]> is used to treat swelling caused by accumulated fluid in body tissues (oedema).

In addition, <[Invented name]> 2.5 mg and 5 mg tablets are used to treat high blood pressure.

This medicine is a diuretic (increase passing of urine), but with the dosage that is relevant for blood pressure treatment has a weak diuretic effect. The diuretic effect occurs within 1 hour with maximum effect after 2-3 hours and lasts up to 12 hours. Maximum blood pressure lowering effect with repeated dosing is seen after up to 10-12 weeks.

<[Invented name]> is indicated in adults and adolescents over 12 years of age.

2. What you need to know before you take <[Invented name]>

Do not take <[Invented name]> if you

- are allergic to torasemide or any of the other ingredients of this medicine (listed in section 6);
- are allergic to sulphonylureas (medicines used to treat diabetes);
- have severe liver disease;
- have reduced blood volume;
- have no urine production;
- have low blood pressure.

Warnings and precautions

Talk to your doctor or pharmacist before taking <[Invented name]> if you:

- have low levels of potassium and sodium in your blood;
- have urination problems;
- are dehydrated;

- have impaired kidney function;
- have an irregular heartbeat;
- have diabetes;
- have cirrhosis of the liver or fluid in the abdomen.

Children and adolescents

<[Invented name]> should not be used by children under 12 years of age.

Other medicines and <[Invented name]>

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

<[Invented name]> may affect or be affected if taken at the same time with the following medicines:

- probenecid (treatment for gout);
- acetylsalicylic acid (analgesic);
- coumarin-type blood thinners (such as warfarin);
- certain remedies for heart disease such as digitalis glycosides and ACE inhibitors;
- anti-diabetic medicines;
- cholestyramine (cholesterol and triglyceride lowering medicines);
- certain medicines for infections such as gentamicin, tobramycin and cephalosporins;
- certain non-steroidal anti-inflammatory/anti-rheumatic drugs (NSAIDs);
- cisplatin (cytostatic – to treat cancer);
- lithium (antipsychotic);
- laxatives;
- glucocorticoids and mineralocorticoids;
- theophylline (for e.g. asthma);
- medicines to relax your muscles (muscle relaxants).

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.

There is a risk that the fetus is affected. Therefore, consult your doctor before taking <[Invented name]> during pregnancy.

It is not known if torasemide passes into breast milk. Therefore consult a doctor before taking this medicine while breast-feeding.

Driving and using machines

<[Invented name]> may impair reactivity. This is especially true at the beginning of the treatment or when the treatment is changed.

<[Invented name]> 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 <[Invented name]>

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

High blood pressure

The recommended dose for adults and adolescents over 12 years of age with high blood pressure is 2.5 mg daily, preferably with breakfast. If necessary, your doctor may increase the dose to a maximum of 5 mg once daily.

Swelling (oedema)

Usual dose for adults and adolescents over 12 years of age with oedema caused by heart or liver failure is 5-10 mg daily, preferably with breakfast. If necessary, the doctor may increase the dose to 20 mg per day or rarely 40 mg per day.

Usual dose for adults and adolescents over 12 years of age with oedema caused by lower kidney function is 20 mg daily, preferably with breakfast. The doctor can increase the dose to 50 mg daily and then, if necessary, gradually increase up to 200 mg once daily.

How to take the tablets

The tablets should be swallowed with a little liquid and should not be chewed. The tablets should preferably be taken in the morning. They can be taken with or without food.

If you take more <[Invented name]> than you should

If you have ingested too much medicine or if for example a child ingested the medicine accidentally, contact a doctor immediately for risk assessment and advice.

If you forget to take <[Invented name]>

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

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.

Stop taking <[Invented name]> and contact a doctor immediately or consult your nearest emergency department if you experience any of the following symptoms:

- Extremely severe and serious skin side effects such as Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported (frequency cannot be estimated from the available data) when taking <[Invented name]>. The skin side effects may consist of rash with or without blisters. Skin redness, sores or swelling in the mouth, throat, eyes, nose and around the genitals as well as fever and flu-like symptoms may also occur. The skin rash can develop into severe widespread skin damage (skin detachment of the epidermis and superficial mucous membranes) with life-threatening consequences.

Other side effects that may occur:

Common (may affect up to 1 in 10 people):

- headache;
- dizziness;
- fatigue (tiredness).

Uncommon (may affect up to 1 in 100 people):

- decreased potassium levels in the blood;
- liver problems;
- bladder problems;
- elevated levels of blood sugar, blood triglycerides and cholesterol;
- overproduction of uric acid;
- loss of appetite;
- weakness;
- stomach or muscle problems;
- vomiting, diarrhoea, constipation, nausea;
- muscle cramps.

Rare (may affect up to 1 in 1 000 people):

- myocardial infarction (heart attack), irregular heartbeat, angina (chest pain);
- altered levels of creatinine, urea and sodium in the blood;
- changes in blood count;
- hypersensitivity to sunlight;
- itching, hives (urticaria);
- hearing loss, tinnitus (ringing in the ears);
- pins and needles and tingling in the arms and legs;
- dry mouth.

Not known (frequency cannot be estimated from the available data):

- brain infarction (stroke), blood clot;
- pancreatitis (inflammation of the pancreas);
- visual disturbances;
- fainting;
- confusion.

Reporting of side effects

If you get any side effects, talk to your doctor 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 <[Invented name]>

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.

This medicine 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 <[Invented name]> contains

- The active substance is torasemide.
<[Invented name]> 2.5 mg tablets: Each tablet contains 2.5 mg of torasemide.
<[Invented name]> 5 mg tablets: Each tablet contains 5 mg of torasemide.
<[Invented name]> 10 mg tablets: Each tablet contains 10 mg of torasemide.
<[Invented name]> 20 mg tablets: Each tablet contains 20 mg of torasemide.
- The other ingredients are lactose monohydrate, hypromellose (E464), sodium starch glycolate (type A), colloidal anhydrous silica and sodium stearyl fumarate.

What <[Invented name]> looks like and contents of the pack

<[Invented name]> 2.5 mg tablets: White to off-white round tablet of approx. 5 mm diameter.

<[Invented name]> 5 mg tablets: White to off-white oblong tablet of dimensions approx. 9 × 4 mm with score line on one side. The tablet can be divided into equal doses.

<[Invented name]> 10 mg tablets: White to off-white round tablet of approx. 9 mm diameter with a debossed “e” in the middle of one side.

<[Invented name]> 20 mg tablets: White to off-white oblong tablet of dimensions approx. 14 × 7 mm.

PVC/Alu foil blisters.

<[Invented name]> 10 mg tablets: 14, 30 tablets

<[Invented name]> 2.5 mg, 5 mg, 20 mg tablets: 14, 28, 30, 56, 60, 84, 90, 98, 112, 120, 150, 168, 180 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden: Torasemid Zentiva

Estonia, Italy, Latvia, Lithuania: Torasemide Zentiva

Bulgaria: Систонал

Poland: Ebozan

This leaflet was last revised 2024-05-13.