

Package leaflet: Information for the patient

Torsemide Sandoz 5 mg tablets
Torsemide Sandoz 10 mg tablets
Torsemide Sandoz 20 mg tablets

Torsemide

Read the entire package leaflet carefully before you start taking this medicine because it contains important information.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this package leaflet. See section 4.

What is in this package leaflet

1. What is Torsemide Sandoz and what is it used for?
2. What should you consider before taking Torsemide Sandoz?
3. How to take Torsemide Sandoz
4. What side effects are possible?
5. How to store Torsemide Sandoz
6. Contents of the pack and other information

1. What is Torsemide Sandoz and what is it used for?

Torsemide Sandoz 5 mg tablets are used for the treatment of:

High blood pressure

Swelling caused by too much water in the body (edema) occur

Torsemide Sandoz 10 mg tablets are used for the treatment of:

Swelling caused by too much water in the body (edema) occur

Torsemide Sandoz 20 mg tablets are used for the treatment of:

Swelling caused by too much water in the body (edema)

Torsemide is a diuretic, a medication that increases urine output.

2. What should you consider before taking Torsemide Sandoz?

Torsemide Sandoz must not be taken

if you are allergic to:

- Torsemide or any of the other ingredients of this medicine listed in section 6.
- similar medicines known as "sulfonylureas" used to treat high blood sugar, with active substances whose names mainly end in "-mid"

in kidney failure with insufficient urine production

in cases of severe liver dysfunction with loss of consciousness

in cases of low blood pressure

reduced blood volume

during breastfeeding
in cases of low potassium or sodium levels in the blood
in cases of severe urinary excretion disorders, for example, caused by an enlarged prostate gland □ in cases of gout
in cases of irregular heartbeat
when taking medications for the treatment of infections, such as cefixime, cefuroxime, cefaclor, cephalexin, cefadroxil, cefpodoxime proxetil, kanamycin, neomycin, gentamicin, amikacin, or tobramycin
in cases of reduced kidney function due to medications that damage the kidneys

Warnings and precautions

Please talk to your doctor before taking Torasemide Sandoz if any of the following apply to you:

abnormal changes in the body's acid-base balance
abnormal changes in blood cell count
diabetes
taking lithium, a medication for the treatment of depression

If you use torasemide continuously, your doctor will regularly monitor your blood values, especially if you are taking other medications or if you have diabetes or heart rhythm disorders.

Children and adolescents

The use of Torasemide Sandoz in children and adolescents under 18 years of age is not recommended.

Taking Torasemide Sandoz with other medicines

Inform your doctor or pharmacist if you are taking, have recently taken, or intend to take other medicines.

The following medicines can affect or be affected by Torasemide Sandoz:

Medicines for the treatment of high blood pressure, especially medicines with active ingredients ending in "-pril"

Medicines to strengthen the heart's pumping ability, such as digitoxin, digoxin, or methyl digoxin

Medicines for the treatment of diabetes

Probenecid, a medicine for the treatment of gout

Medicines for the treatment of inflammation and pain, such as acetylsalicylic acid or indomethacin

Sulfasalazine, mesalazine, or olsalazine, medicines for the treatment of chronic inflammatory bowel diseases

Medicines for the treatment of infections, such as cefixime, cefuroxime, cefaclor, cephalexin, cefadroxil, cefpodoxime proxetil, kanamycin, neomycin, gentamicin, amikacin, or tobramycin

Platinum compounds, such as cisplatin (a medicine for the treatment of cancer)

Lithium, a medicine for the treatment of depression

Theophylline, a medicine for the treatment of asthma

Some muscle relaxant medicines with active ingredients ending in "-curonium" or "-curium"

All medicines for the treatment of constipation

Cortisone-containing medicines, such as hydrocortisone, prednisone, or prednisolone
Cholestyramine, a medicine for lowering blood lipid levels
Adrenaline or noradrenaline, medicines for increasing blood pressure
Warfarin, a medicine for the treatment of blood clots

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy

Torasemide Sandoz should only be taken during pregnancy if your doctor considers it absolutely necessary. In this case, the lowest possible dose must be used.

Breastfeeding

Torasemide Sandoz should not be used by breastfeeding mothers as it may harm the baby.

Ability to drive and use machines

Dizziness or lightheadedness may occur when taking Torasemide Sandoz, especially at the start of treatment, when increasing the dose, when switching medications, when starting another medication, or when consuming alcohol simultaneously. If your attention is impaired, you must not drive vehicles or operate machines.

Torasemide Sandoz contains lactose

This medicine contains lactose, a type of sugar. Please only take this medicine after consulting your doctor if you know you have a sugar intolerance.

3. How to take Torasemide Sandoz?

Always take this medicine exactly as agreed with your doctor. Ask your doctor or pharmacist if you are unsure.

The recommended dose is:

Torasemide Sandoz 5 mg tablets

Treatment of high blood pressure

½ tablet once daily

If necessary, your doctor may increase the dose to 1 tablet once daily at the earliest after two months of treatment.

Treatment of swelling caused by too much water in the body (edema)

1 tablet once daily

If necessary, your doctor may gradually increase the dose to 4 tablets once daily.

Splitting the tablet:

The tablet can be divided into equal doses.

Place the tablet with the score line facing up on a hard, flat surface. Press with your finger on the center of the tablet, and it will break into two equal halves.

Torsemide Sandoz 10 mg tablets

Treatment of swelling caused by too much water in the body (edema)

½ tablet once daily

If necessary, your doctor may gradually increase the dose to 2 tablets once daily.

Splitting the tablet:

The tablet can be divided into equal doses.

Place the tablet with the score line facing up on a hard, flat surface. Press with one finger on the left and right side of the individual score line, and the tablet will break into two equal halves.

Torsemide Sandoz 20 mg tablets

Treatment of swelling caused by too much water in the body (edema)

¼ tablet once daily

If necessary, your doctor may gradually increase the dose to 1 tablet once daily.

Splitting the tablet:

The tablet can be divided into equal doses.

Place the tablet with the score line facing up on a hard, flat surface. Press with your finger on the center of the tablet, and it will break into four equal parts.

Use in children and adolescents

There is insufficient experience with the use of torsemide in children and adolescents, therefore this medication is not recommended for children and adolescents under 18 years of age.

Impaired liver function that is not severe

Your doctor will treat you cautiously, as the level of torsemide in the blood could increase.

Method of administration

Swallow the tablets every morning outside of meals unchewed with 100 ml of water, which is about half a glass.

Duration of treatment

Your treating doctor will decide on this. Torsemide Sandoz can be used for several years or as long as it takes for the excess fluid to disappear from the tissue.

If you have taken more Torsemide Sandoz than you should If you have used more Torsemide Sandoz, contact your doctor, pharmacist, or the poison control center (070/245.245) immediately.

An overdose can cause increased urine production, drowsiness, confusion, weakness, dizziness, hypotension, circulatory collapse, and stomach discomfort.

Always take the remaining tablets and the box with you; this makes it easier to identify the tablets.

If you forget to take Torasemide Sandoz

Take the missed dose as soon as possible on the same day or take the next dose normally on the following day. Do not take a double dose if you have forgotten the previous intake.

If you stop taking Torasemide Sandoz

Never stop taking Torasemide Sandoz without your doctor's consent, as this can seriously harm you and limit the therapeutic effect.

If you have further questions about taking this medication, contact your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, this medicine can have side effects, but they do not have to occur in everyone.

Side effects can occur with the following frequency:

Common: may affect up to 1 in 10 people

- Disorders of body water and mineral balance, especially if salt intake is significantly restricted

- Excessive alkalinity in the body

- Muscle cramps

- Increased levels of uric acid, sugar, and fats in the blood

- Decreased potassium or sodium levels in the blood

- Reduced blood volume

- Stomach and/or intestinal disorders, such as loss of appetite, stomach pain, nausea, vomiting, diarrhea, constipation

- Increase in certain liver enzyme levels, such as gamma-GT

- Headaches

- Dizziness

- Fatigue

- Weakness

Occasionally: may affect up to 1 in 100 people

- Increase in blood urea and creatinine concentrations

- Dry mouth

- Tingling or prickling in arms and legs

- Difficulty urinating (e.g., due to an enlarged prostate)

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

- Narrowed or obstructed blood vessels due to thickening of the blood

- lower blood pressure than normal

- circulatory problems, especially when standing up

- irregular heartbeat

- angina pectoris, a disease often characterized by severe chest pain is

- heart attack

- fainting

- inflammation of the pancreas

- allergic reactions with itching and rash

- increased sensitivity of the skin to light

severe skin reactions
reduced number of red and white blood cells and platelets
visual disturbances
ringing or buzzing in the ears
hearing loss

Not known: frequency cannot be estimated from the available data
insufficient blood supply to the brain
confusion

reporting of side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this package leaflet. You can also report side effects directly to the Federal Agency for Medicines and Health Products, Vigilance Department, EUROSTATION II, Victor Hortaplein 40/40, B-1060 BRUSSELS. Website: www.fagg-afmps.be, Email: patientinfo@fagg-afmps.be. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Torasemide Sandoz?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date which is stated on the blister pack and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. This will help protect the environment.

6. Contents of the pack and other information

What Torasemide Sandoz contains

- The active substance is torasemide.
Each tablet contains 5 mg of torasemide.
Each tablet contains 10 mg of torasemide.
Each tablet contains 20 mg of torasemide.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, magnesium stearate, corn starch, colloidal silicon dioxide.

What Torasemide Sandoz looks like and contents of the pack 5 mg tablets:

The Torasemide Sandoz tablet is a round, white to off-white tablet with a score line.

10 mg tablets:

The Torasemide Sandoz tablet is a round, white to off-white tablet with a cross score line.

20 mg tablets:

The Torasemide Sandoz tablet is a round, white to off-white tablet with a cross score line.

Pack sizes: 10, 14, 20, 28, 30, 50, 56, 100, 400 (20 x 20) tablets.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Sandoz nv/sa, Telecom Gardens, Medialaan 40, B-1800 Vilvoorde

Manufacturer

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany

LEK S.A., ul. Domaniewska 50 C, 02-672 Warsaw, Poland

Lek S.A, ul. Podlipie 16, 95-010 Stryków, Poland

Marketing Authorization Numbers

Torsemide Sandoz 5 mg tablets: BE259813 (Alu/Alu blister pack) and
BE259822 (PVC/COC/PVDC/Alu blister pack)

Torsemide Sandoz 10 mg tablets: BE259795 (Alu/Alu blister pack) and
BE259804 (PVC/COC/PVDC/Alu blister pack)

Torsemide Sandoz 20 mg tablets: BE259777 (Alu/Alu blister pack) and
BE259786 (PVC/COC/PVDC/Alu blister pack)

Type of Supply

Prescription only

This medicinal product is authorized in the Member States of the European Economic Area (EEA) under the following names:

BE	Torsemide Sandoz 5 mg tablets Torsemide Sandoz 10 mg tablets Torsemide Sandoz 20 mg tablets
BG	TORAZIDEX 5 MG TABLETS TORAZIDEX 10 MG TABLETS EE Torsemide HEXAL
DE	Torsemide Sandoz 20 mg tablets
IT	TORASEMIDE HEXAL
LT	Toridium 10 mg tablets
LV	Torsemide HEXAL 10 mg tablets
SE	Torahexal 5 mg tablet Torahexal 10 mg tablet Torahexal 20 mg tablet

This package leaflet was last revised in 10/2020.