PACKAGE LEAFLET

Package leaflet: Information for the patient

Furosemide Teva 125 mg, tabletten
Furosemide Teva 250 mg, tabletten
Furosemide Teva 500 mg, tabletten
furosemide

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 [Product name] is and what it is used for

[Product name] belongs to a group of medicines known as diuretics (water tablets). Diuretics make you pass more water (urine).

[Product name] should only be used in adult patients with fluid retention (oedema) and severely reduced glomerular filtration (glomerular filtration rate (GFR) < 20 ml/min).

2. What you need to know before you take [Product name]

Do not take [Product name]
- if you are allergic to furosemide, sulfonamides (used to treat bacterial infections, diabetes, increased eye pressure or to increase urine output) or any of the other ingredients of this medicine (listed in section 6)
- if you have normal or mildly to moderately reduced kidney function with a GFR greater than 20 ml/min, because of the risk of severe fluid and salt (electrolyte) loss
- if you have kidney failure and your kidneys do not produce urine at all (anuria)
- if you have serious liver disease (Precoma or coma associated with brain damage caused by liver problems (hepatic encephalopathy))
- if you have potassium deficiency
- if you have sodium deficiency
- if you have been told you have a low blood volume (hypovolaemia) or body water (dehydration)
- if you are breast-feeding (see section “Pregnancy and breast-feeding”)
- if your body is unable to produce adequate amounts of adrenal hormones (Addison's disease)
- if you have taken too much (overdose) cardiac glycoside medication (e.g. digoxin, digitoxin)

Warnings and precautions
Talk to your doctor or pharmacist before taking [Product name]
- if you have low blood pressure (hypotension)

- if you have or suspect you may have diabetes: regular monitoring of your blood sugar levels is necessary
- if you have gout: regular monitoring of your blood uric acid levels is necessary
- if you have low levels of protein in your blood (hypoproteinaemia), for instance if you have nephrotic syndrome (loss of protein, disturbance of fat metabolism and fluid retention): your doctor will need to adjust your dose carefully, and you must follow the instructions exactly
- if you have liver cirrhosis (tiredness, weakness, water retention, feeling or being sick, loss of weight or appetite, yellowing skin or eyes, itch) as well as reduced kidney function
- if you have circulation problems in the brain (cerebrovascular circulatory disorders) or heart vessels (coronary heart disease): the risks associated with a possible fall in blood pressure are higher
- if you are elderly, if you are on other medications which can cause the drop the blood pressure and if you have other medical conditions that are risks for the drop of blood pressure
- if you have significant difficulty urinating because of a blockage in the flow of urine (urinary tract obstruction)

Your doctor will want to monitor you, and may take blood for testing while you are taking this medicine.

In patients with impaired kidney function resulting in frequent urination, you must ensure that you take sufficient (by drinking).

In patients with bladder emptying disorders (*e.g.* prostate enlargement), [Product name] may only be used if free urine outflow is ensured, since a sudden onset of urinary flow can lead to a urinary blockage (urinary retention) with overstretching of the bladder.

In patients with an existing decrease in blood acidity (increased pH) due to acid loss (metabolic alkalosis), this can be worsened by furosemide. If you use furosemide for a long period of time, your doctor will monitor you regularly.

Close monitoring is necessary if you have a high risk of developing electrolyte disturbances (*e.g.* if you have cirrhosis of the liver, or you take corticosteroid medicines or use laxatives a lot, or you have a limited diet) or if you lose a lot of fluids (*e.g.* if you experience significant vomiting, diarrhoea or intensive sweating): any blood or fluid loss (hypovolaemia or dehydration) or any electrolyte or acid-base imbalance in your body will need to be corrected, which may require your doctor to temporarily stop your treatment with [Product name]. Your doctor will check your blood regularly. If you use furosemide long-term, your doctor may prescribe a potassium-rich diet (potatoes, bananas, tomatoes, citrus fruits, fruit juices, dried fruit, cauliflower, and spinach).

You should not lose more than 1 kg a day in body weight due to increased urination, regardless of how much urine you pass.

Your doctor may need to check the effect of your treatment with [Product name] periodically by temporarily stopping it.

Tell your doctor if you are going to undergo an X-ray examination with contrast media. The kidney side effects of contrast media used in some X-ray examinations may worsen with [Product name]

Sun or UV exposure: Tell your doctor if you have an exaggerated skin reaction after sun or UV exposure (photosensitivity) as stopping treatment may be necessary.

Children
[Product name] may cause calcium deposits in kidneys or kidney stones in premature babies and increases the risk of a foetal blood vessel called the ductus arteriosus remaining open after birth, when it should normally close, in premature babies with breathing difficulties. 125 mg, 250 mg and 500 mg strengths are not recommended for use in children and adolescents under 18 years of age.

Other medicines and [Product name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

[Product name] can affect the way some of the other medicines work. Likewise, some medications can affect how [Product name] works.

It is particularly important to inform your doctor if you are taking:
- glucocorticoids ("cortisone"), carbenoxolone or laxatives may increase potassium loss and therefore the risk of potassium deficiency
- anti-inflammatory medicines (NSAIDs *e.g.* indomethacin, acetylsalicylic acid) may reduce the effect of [Product name] and increase the risk of acute kidney failure in the event of blood or fluid loss (hypovolaemia or dehydration)
- probenecid (for gout), methotrexate (for arthritis and to suppress the immune system) and other medicines excreted by the kidneys may reduce the effect of [Product name]
- phenytoin (for epilepsy and some forms of pain) may reduce the effect of [Product name]
- carbamazepine (for epilepsy and some forms of psychiatric illness) may increase sodium loss and therefore the risk of sodium deficiency
- sucralfate (an antacid) reduces the uptake of [Product name] from the intestines and may thus weaken its effect: you should take sucralfate and [Product name] at least 2 hours apart
- aliskiren (for high blood pressure)

[Product name] may influence the effect of the following medicines:
- some heart medicines (glycosides) may have a stronger effect owing to the potassium and magnesium deficiency which [Product name] may cause. Medicines which affect the heart's rhythm (*e.g.* terfenadine for allergies, some medicines used to treat abnormal heart rhythms) have a higher risk of causing heart rhythm abnormalities if they are used at the same time as [Product name] or in the event of electrolyte disorders
- the side effects of high-dose salicylates (for pain) may be worsened by [Product name]
- the side effects of some medicines on the kidneys may be worsened (*e.g.* antibiotics such as aminoglycosides, cephalosporins, polymyxins). [Product name] together with high doses of some cephalosporins may cause worsening of kidney function
- the side effects of some medicines (*e.g.* aminoglycosides such as kanamycin, gentamicin, tobramycin) on hearing may be worsened by [Product name]. These side effects are not always reversible. [Product name] should therefore not be used at the same time as these medicines
- the risk of damage to hearing may be increased when cisplatin (for cancer) and [Product name] are used together. Caution is required as the side effects of cisplatin on the kidney may be increased.
- the side effects of lithium (for certain forms of depression) on the heart and nervous system may be worsened if [Product name] is used at the same time. Your doctor should monitor your blood lithium levels if you take these medicines together
- your blood pressure may fall if you take [Product name] with other medicines with the potential to lower the blood pressure, such as blood presume medicines or other diuretics. Medicines called ACE inhibitors and angiotensin II receptor blockers especially may lead to a massive drop in blood pressure to the point of shock and a worsening of kidney function (in isolated cases to the point of kidney failure) when the first dose is taken or the first time a higher dose is used. Your doctor may tell you to stop taking [Product name] for at least 3 days before you start taking an ACE inhibitor or an angiotensin II receptor blocker or before the dose of these medicines is increased
- [Product name] may reduce the removal of probenecid, methotrexate or other medicines by the kidneys, which may lead to increased levels of these medicines in the blood and possible side effects
- the effect of theophylline (for asthma) or curare-type muscle relaxants may be increased if they are used at the same time as [Product name]
- antidiabetic medicines and products that increase blood pressure (sympathomimetics *e.g.* adrenaline, noradrenaline) may not work as well with [Product name]
- caution is required when using risperidone in elderly patients with dementia at the same time as [Product name]. It is very important that you avoid becoming dehydrated. In clinical studies in elderly patients with dementia, more patients died on risperidone with furosemide than on either treatment used alone
- concomitant use of thyroid hormones (*e.g.* L-thyroxine) and high doses of furosemide can affect

the thyroid hormone levels. Your doctor should monitor your thyroid hormone levels if you take these medicines together
- concomitant use of ciclosporin A (medicine used to prevent transplant rejection) and furosemide is associated with an increased risk of arthritis caused by gout, as a result of furosemide-induced increases in blood levels of uric acid and ciclosporin's interference with the excretion of uric acid by the kidneys
- in individual cases, after intravenous administration of furosemide within 24 hours after taking chloral hydrate (a drug with sedative properties), flushing, sweating, restlessness, nausea and an increase in blood pressure and heart rate (tachycardia) can occur. The concomitant use of furosemide and chloral hydrate should therefore be avoided

[Product name] with food and drink
Avoid large amounts of liquorice products when taking [Product name], as this may result in increased loss of potassium.

Pregnancy and breastfeeding

Pregnancy
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.

You should not take [Product name] if you are pregnant unless your doctor considers it to be essential as furosemide crosses the placenta.

Breast-feeding
You must not take [Product name] if you are breast-feeding as it will pass into your milk and inhibit your milk production. You must stop breast-feeding in order to take [Product name].

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines
This medicine may impair your ability to react to such a degree that it may influence your capacity to drive and use machines. This is especially true at the beginning of treatment, when the dose is increased or the medicine switched, and in combination with alcohol.

[Product name] contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take [Product 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.

Adults
The starting dose of [Product name] is 250 mg furosemide.

Your doctor will then adjust your dose gradually, at intervals of 4 to 6 hours. Your doctor will periodically check your urine output and electrolyte and fluid balance.

The recommended maximum daily dose of furosemide in adults is 1,500 mg when taken orally.

If you have chronic kidney impairment, your doctor will adjust the dose carefully in order to reduce your fluid retention (oedema).

Use in children and adolescents
The safety and efficacy of [Product name] in children and adolescents under 18 years of age have not been established. No data are available: other pharmaceutical forms/strengths may be more appropriate for administration to these patients.

Elderly and patients with hepatic impairment
Your doctor will carefully adjust your dose according to how you respond to the treatment.

Method of administration
The tablets should be taken in the morning without food, without chewing, with a sufficient amount of fluid (*e.g.* a glass of water).

Your doctor will decide how long you should keep taking [Product name] depending on the nature and severity of your illness.

If you take more [Product name] than you should
If you take too much [Product name] or you suspect an overdose, contact a doctor immediately. The signs of an acute overdose are related to the loss of salt and fluid: low blood pressure (hypotension), feeling dizzy or light-headed on standing up (orthostatic regulation problems), electrolyte disturbances (reduced potassium, sodium and chloride levels) or an increase in the pH value of the blood (alkalosis).

Severe fluid loss may lead to dehydration and collapse from reduced blood volume with concentration of the blood and an increased risk of blood clots. In the event of rapid fluid and electrolyte loss, confusion and delirium may occur.

If you forget to take [Product name]
Carry on with the usual dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking [Product name]
Do not stop taking [Product name] unless your doctor tells you to or your treatment may be unsuccessful.

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 [Product name] and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:
- loss of hair, suddenly appearing red swollen area on the skin with numerous small pustules (acute generalized exanthematous pustulosis - AGEP)
- widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome)
- severe allergic reaction (anaphylactic shock): the first signs are a skin reaction with flushing or hives, unrest, headache, sweating, feeling sick and a bluish tinge to the skin (cyanosis)
- pins and needles (paraesthesia); life-threatening form of unconsciousness (hyperosmolar coma)
- certain severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis)

You must stop taking [Product name] at the first signs of an allergic (hypersensitivity) reaction.
Blood glucose levels may increase during treatment with [Product name] which may lead to worsened control of diabetes or the overt manifestation of previously silent diabetes.

[Product name] may cause calcium deposits or stones in the kidneys of premature babies and increases

the risk of a fetal blood vessel called the ductus arteriosus remaining open after birth when it should normally close, in premature babies with breathing difficulties.

If you develop any of these side effects, please contact your doctor as soon as possible. If a side effect develops suddenly or becomes serious, please seek medical advice immediately as some side effects may under certain circumstances be life threatening.

Very common side effects (may affect more than 1 in 10 people):
- electrolyte or fluid disorders which may lead to
  - sodium deficiency (hyponatraemia, most frequently characterised by apathy, leg cramps, loss of appetite, weakness, sleepiness, vomiting and confusion)
  - potassium deficiency (hypokalaemia characterised most frequently by muscle weakness, pins and needles, slight paralysis, vomiting, constipation, bloating, frequent urination, excessive thirst and abnormal heart rhythms, and, in severe cases, intestinal obstruction or altered consciousness including coma)
  - calcium deficiency, sometimes leading to muscle twitching and cramps (tetany)
  - magnesium deficiency, rarely leading to muscle twitching and cramps (tetany) or heart rhythms abnormalities
  - increased blood pH (metabolic alkalosis)
  - significant fluid loss may lead to circulatory disorders chiefly associated with headache, dizziness, visual disturbances, mouth dryness and thirst, low blood pressure (hypotension) and feeling dizzy or light-headed on standing up (orthostatic regulation problems), especially in the elderly and in children. Severe fluid loss may lead to dehydration and collapse from reduced blood volume with concentration of the blood and an increased risk of blood clots.
- increased blood creatinine
- increased blood triglycerides

Common side effects (may affect up to 1 in 10 people):
- thickening of blood (haemoconcentration)
- hyponatraemia, hypochloraemia, hypokalaemia
- increase blood cholesterol
- increased blood uric acid levels which may lead to gout in some patients
- increased urine volume
- brain disorder characterized by, for example, convulsions and decreased consciousness due to insufficient liver function (hepatic encephalopathy)

Uncommon side effects (may affect up to 1 in 100 people):
- low numbers of blood platelets (thrombocytopenia)
- itching (pruritus), skin and mucous membrane reactions: redness, blisters, scales (*e.g.* bullous exanthema, hives, purpura, erythema multiforme, bullous pemphigoid, exfoliative dermatitis), increased sensitivity to light (photosensitivity)
- deafness (sometimes irreversible)
- hearing impairment (usually reversible)
- feeling sick (nausea)

Rare side effects (may affect up to 1 in 1,000 people):
- high or low numbers of white blood cells (eosinophilia or leucopenia)
- fever
- inflammation of blood vessels (vasculitis)
- inflammation of the kidneys (interstitial nephritis)
- ringing or buzzing in the ears (tinnitus)
- digestive problems (*e.g.* being sick, diarrhoea)

Very rare effects (may affect up to 1 in 10,000 people):
- anaemia due to loss (haemolytic anaemia) or reduced production (aplastic anaemia) of red blood cells, very low numbers of certain white blood cells with an increased risk of infection and severe general symptoms (agranulocytosis)

- inflammation of the pancreas, inhibition of the bile flow (intrahepatic cholestasis), increased liver function test results (transaminases)

Not known (frequency cannot be estimated from the available data):
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- worsening or triggering of systemic lupus erythematosus (a disease in which the immune system attacks the body), headache
- decreased calcium and/or magnesium in your blood
- decreased acidity (increased pH) in the blood due to acid loss (metabolic alkalosis)
- Pseudo-Bartter syndrome which can result in fluid retention in body tissues
- lichenoid reactions characterized as small, itchy, reddish-purple, polygonal lesions on the skin, genitals, or in the mouth
- breakdown of muscles often leading to kidney damage (rhabdomyolysis), often in association with severe low blood potassium levels
- increased urine sodium
- increase urine chloride
- increase blood urea
- sudden retention of urine in the bladder due to impaired bladder emptying (urinary retention) in patients with partial blockage of the urinary tract (*e.g.* in prostate hyperplasia, hydronephrosis, ureteral stenosis)
- renal failure
- formation of blood clots in the blood vessels (thrombosis) particularly in elderly patients

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 [Product 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 and blister after "EXP". The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. Keep blisters in the outer carton.

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 [Product name] contains

- The active substance is furosemide.
- Each tablet contains 125 mg of furosemide.
  Each tablet contains 250 mg of furosemide.
  Each tablet contains 500 mg of furosemide.
- **The other ingredients** are Cellulose, microcrystalline E460, lactose monohydrate, povidone K90 E1201, sodium starch glycolate Type A and magnesium stearate E470b.

What [Product name] looks like and contents of the pack

[Product name] 125 mg tablets are white or almost white, approx. 9 mm round biconvex tablets, with

breakline on one side, the other side is plain.
[Product name] 250 mg tablets are white or almost white, approx. 11 mm round biconvex tablets, with two crossed breaklines on one side of the tablet, the other side is plain.
[Product name] 500 mg tablets are white or almost white, approx. 14 mm round biconvex tablets, with two crossed breaklines on one side of the tablet, the other side is plain.

[Product name] 125 mg tablets are available in blister packs of 10, 20, 30, 50 or 100 tablets, unit-dose blister packs of 10x1, 20x1, 30x1, 50x1 or 100x1 tablets and bottles of 50, 100, 105 or 200 tablets.

[Product name] 250 mg tablets are available in blister packs of 10, 20, 30, 50 or 100 tablets, unit-dose blister packs of 10x1, 20x1, 30x1 50x1 or 100x1 tablets and bottles of 50, 100, 105 or 200 tablets.

[Product name] 500 mg tablets are available in blister packs of 20, 30, 50 or 100 tablets and bottles of 50, 100, 105 or 200 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder
Teva B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Manufacturer
Teva Operations Poland Sp. z.o.o.
ul. Mogilska 80
31-546 Krakau
Polen

In het register ingeschreven onder
RVG 133838, tabletten 125 mg
RVG 133839, tabletten 250 mg
RVG 133840, tabletten 500 mg

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

Nederland:	Furosemide Teva 125 mg, tablettem
	Furosemide Teva 250 mg, tabletten
	Fureosemide Teva 500 mg, tabletten
Duitsland	Furosemid AbZ 125 mg Tabletten
	Furosemid AbZ 250 mg Tabletten
	Furosemid AbZ 500 mg Tabletten

Deze bijsluiter is voor het laatst goedgekeurd in december 2025.

Other sources of information

<Latest approved information on this medicine is available by scanning the QR code included in the <package leaflet> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website>>