Furosemide, it is very important that you avoid becoming dehydrated. In increase in urine production caused by Furosemide, regardless of how
You should not lose more than 1 kg a day in body weight owing to the
treatment with Furosemide.

• If you have any questions, ask your doctor or pharmacist.
• This guide 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 Furosemide is and what it is used for
2. What you need to know before you take Furosemide
3. How to take Furosemide
4. Possible side effects
5. How to store Furosemide
6. Contents of the pack and other information

What Furosemide is and what it is used for
Furosemide belongs to a group of medicines known as diuretics (water tablets).
You should only use this high-dose formulation if you have severely
reduced kidney function (glomerular filtration rate (GFR) < 20 ml/min).
Furosemide is used to treat reduced urine production (oliguria) in chronic kidney failure.

2. What you need to know before you take Furosemide
• 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.

Tell your doctor if you are undergoing an X-ray examination with contrast media.

Children
Furosemide may cause calcium deposits or stones in the kidneys of premature babies and increase 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. The doctor will therefore need to monitor the baby very closely.

Athletes
Furosemide may cause positive results in drugs tests. The use of Furosemide as a performance-enhancing substance may endanger your health.

Other medicines and Furosemide
Tell your doctor or pharmacist if you are using, have recently used or
might use any other medicines.

The following medicines may influence the effect of Furosemide:
• Glucocorticosteroids (Cortisone), carbamazepine or diazepam 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 Furosemide and increase the risk of acute kidney failure in the event of blood or fluid loss (hypovolaemia or dehydration).
• Probencid (for gout), metoloxate (for arthritis and to suppress the immune system) and other medicines excreted by the kidneys may reduce the effect of Furosemide.
• Phenytion (for epilepsy and some forms of psychiatric illness) may increase sodium loss and therefore the risk of sodium deficiency.
• Sucralfate (for bleeding) reduces the uptake of Furosemide from the intestine and may thus reduce its effect; you should take sucralfate and Furosemide at least 2 hours apart.

Furosemide 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 Furosemide may cause. Medicines which affect the heart’s rhythm (e.g. terfenadine for allergies, some medicines used to treat abnormal blood pressure and heart irregularities) may have a stronger effect on the heart’s rhythm abnormalities if they are used at the same time as Furosemide or in the event of electrolyte disorders.
• The side effects of high-dose salicylates (for pain) may be worsened by Furosemide.
• The side effects of some medicines on the kidneys may be worsened (e.g. antibiotics such as amoxicillin, cephalexin, ciprofloxacin, cotrimoxazole) used together. Caution is required as the side effects of these medicines may be increased when Furosemide is used at the same time.
• The risk of damage to hearing may be increased when cisplatin (for cancer) and Furosemide are used together. Caution is required as the
risk of damage to hearing may be increased if they are used at the same time.
• Phenytoin (for epilepsy and some forms of pain) may reduce the effect
of theophylline (for asthma) or curare-type muscle relaxants (for surgery) and Furosemide are used together. Caution is required as the
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effect of these medicines may be reduced.
You must not take Furosemide if you are breastfeeding as it will pass into your milk and inhibit your milk production. You must stop breast-feeding in order to take Furosemide.

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

### Driving and using machines
Furosemide 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 if you consume alcohol during treatment.

### Furosemide contains lactose.
Furosemide contains lactose. If you have been intolerant to some sugars, contact your doctor before taking this medicinal product.

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

Your doctor will decide the dose that is right for you, based mainly on how you respond to the treatment. The dose should be as low as possible to achieve the desired effect.

####Adults
The starting dose of Furosemide is half a tablet (250 mg furosemide). Your doctor will then adjust your dose gradually in steps of half a tablet (250 mg) at intervals of 4 to 8 hours, up to a usual maximum dose of 2 tablets (1,000 mg). Your doctor will periodically check your urine output and electrolyte and fluid balance.

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

####Use in children and adolescents
Furosemide is not recommended for use in children and adolescents under 18 years of age due to insufficient data on safety and effectiveness: 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 Furosemide, depending on the nature and severity of your illness.

####If you take more Furosemide than you should
If you take too much Furosemide, 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 abnormalities), and confusion.

####If you forget to take Furosemide
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 Furosemide
Do not stop taking Furosemide 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.

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

####Common side effects (may affect up to 1 in 10 people):
- Electrolyte or fluid disorders which may lead to:
  - sodium deficiency (hypotrematxia, 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, sligh paralysis, vomiting, constipation, bloating, frequent urination, excessive thirst and abnormal heart rhythms, and, in severe cases, intestinal obstruction or altered consciousness)
  - 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.
- Raised blood uric acid levels which may lead to gout in some patients

### Uncommon side effects (may affect up to 1 in 100 people):
- Low numbers of blood platelets (thrombocytopenia)
- Itching, skin and mucous membrane reactions: redness, blisters, scales (e.g. bullous exanthema, livers, purpura, erythema multiforme, bullous pemphigoid, exfoliative dermatitis), increased sensitivity to light (photosensitivity)
- Greatness (sometimes irreversible)

####Rare side effects (may affect up to 1 in 1,000 people):
- High or low numbers of white blood cells (leucopenia or leucocytosis)
- Inflammation of blood vessels (vasculitis)
- Inflammation of the kidneys (interstitial nephritis)
- Severe allergic reaction (anaphylactic shock): the first signs are a skin reaction with itching, swelling or oedema, urinet, headache, sweating, feeling sick and a bluish tinge to the skin (cyanosis)
- Pits and needles (parethesia)
- Usually reversible hearing disorders and/or ringing or buzzing in the ears (tinnitus)
- Digestive problems (e.g. feeling or 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 (anraunacytlosis)
- Inflammation of the pancreas, inhibition of bile flow (intrahepatic cholestasis), increased liver function test results (transaminases)
- Certain severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis)

####Not known (frequency cannot be estimated from the available data):
- Acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)

Blood glucose levels may increase during treatment with Furosemide, which may lead to worsened control of diabetes or the overt manifestation of previously silent diabetes. Blood fat (cholesterol and triglycerides), creatinine or urea levels may also increase.

####Brain disease (hepatic encephalopathy) may develop in patients with advanced liver disease.
Symptoms of obstruction in the urine outflow tract (e.g. enlarged prostate or narrowing of the ureter, the tube that connects the kidney and bladder) may develop or worsen, with the potential for urine retention and associated complications.

Furosemide may cause calcium deposits or stones in the kidneys of patients with chronic kidney impairment, your doctor will adjust the dose downwards.

### What Furosemide is and what it is used for
Furosemide is prescribed for you only. Do not pass it on to others. If you have any questions, ask your doctor or pharmacist.

### What Furosemide looks like and contents of the pack
The tablet contains furosemide.

####What Furosemide contains
- The active substance is furosemide. Each tablet contains 500 mg furosemide.
- The other ingredients are lactose monohydrate, maize starch, silica collodial anhydrous, talc, magnesium stearate and iron oxide yellow (E172).

### Marketing Authorisation Holder and Manufacturer
TEVA UK Limited, Eastbourne BN22 9AG, United Kingdom

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