Package leaflet: Information for the user

Furosemide Clonmel 20 mg tablets
Furosemide Clonmel 40 mg tablets
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 Furosemide Clonmel is and what it is used for
2. What you need to know before you take Furosemide Clonmel
3. How to take Furosemide Clonmel
4. Possible side effects
5. How to store Furosemide Clonmel
6. Contents of the pack and other information

1. What Furosemide Clonmel is and what it is used for

Furosemide Clonmel is a diuretic, a medicine that increases urine output.

Product name] is used to treat:
- swelling caused by excess fluid in the tissues, occurring in patients with:
  – heart disease
  – liver disease (most often in combination with potassium sparing diuretic)
  – kidney disease
  This also includes kidney disease with massive protein loss, increased blood fat levels and swelling through fluid accumulation (nephrotic syndrome). If you have this particular kidney disease, it should be treated first.
- high blood pressure (arterial hypertension).

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

DO NOT take Furosemide Clonmel, if you:
- are allergic to **furosemide** or any of the other ingredients of this medicine (listed in section 6). If you know that you are allergic to **sulfonamides** (e.g. sulfonamide antibiotics or sulfonylureas) you may be also allergic to furosemide.
- have **kidney failure with insufficient urine production**
- have been told that you have a **low blood volume of fluid in your body** or are **dehydrated** (with or without accompanying low blood pressure)
- have severe electrolyte deficiency (e.g. **very low potassium or sodium levels in your blood** as shown in blood test)
- are **breast-feeding**
- have **severe problems with your liver** (hepatic cirrhosis or encephalopathy)
- have liver disease (hepatitis or severe liver failure), especially if you also have kidney failure, whether or not requiring dialysis
- have **significant difficulty urinating** due to a blockage of the urinary tract (obstruction of the urinary passages)

Warnings and precautions
Talk to your doctor or pharmacist before taking Furosemide Clonmel.

Your doctor will monitor you or your child carefully in the following cases:
- if you have **low blood pressure** or if you are at risk of a **pronounced fall in blood pressure** (e.g. due to medical conditions like circulatory disorders of the brain or a heart disorder)
- if you have **diabetes** (high blood sugar). Your doctor will check your blood sugar levels regularly.
- If you have **reduced kidney function** with liver disease, known as hepatorenal syndrome. Your doctor may need to adjust your dose of Furosemide Clonmel.
- If you have **severe liver disease** (hepatocellular insufficiency), since it may lead to development of hepatic encephalopathy. Your doctor will check your serum electrolytes levels regularly. If hepatic encephalopathy occurs treatment with furosemide should be discontinued immediately.
- If you have **low levels of protein in your blood** (hypoproteinaemia), especially in the case of nephrotic syndrome. Your doctor will carefully adjust your dose of Furosemide Clonmel.
- If you have **gout**. Your doctor will check your serum uric acid values levels regularly.
- If you are taking **lithium**. Your doctor will check your lithium levels carefully and adjust the dose if necessary.
- If this medicine is to be given to a **premature baby**. The doctor will monitor your child's renal function, perform renal ultrasonography and take other precautions if needed (see also section 4).

Also tell your doctor or pharmacist before taking Furosemide Clonmel if you:
- are **elderly** and/or you are taking other **medications which can cause a drop in blood pressure** and you have other **medical conditions that are risks for a drop of blood pressure** (hypotension).
- are elderly and have dementia and are taking **risperidone** (a medicine to treat schizophrenia)
- have **urinary flow disorders** caused, for example, by an enlarged prostate gland, or reduced urination. Your doctor will carefully monitor your urinary output.
- are at **risk of reduced electrolyte levels and/or abnormal changes in the pH levels of your body,** which can occur if you have lost a lot of fluid through being sick, having diarrhoea or intense sweating, have other diseases (liver or heart disorder) or use other medicines (see subsection "Other medicines and Furosemide Clonmel"). In general, your doctor will monitor your blood levels of electrolytes (especially **potassium, sodium and calcium**), uric acid, glucose and creatinine regularly, especially if you are a high-risk patient and in long-term treatment. Electrolyte and pH level imbalance must be corrected. Your doctor may temporarily stop Furosemide Clonmel treatment.
- have an inflammatory disease which causes joint pain, skin rashes and fever (**systemic lupus erythematosus**). There is a possibility of worsening or triggering the disease.
- are taking **other medicines**, see also subsection "Other medicines and Furosemide Clonmel"

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Furosemide Clonmel.

The weight loss caused by increased urinary excretion should not exceed 1 kg/day, irrespective of the extent of urinary excretion.

To prevent excessive loss of potassium, a diet rich in potassium is recommended, e.g. potatoes, bananas, tomatoes, spinach, dried fruit. Your doctor may also decide to prescribe you potassium supplements.

If you use Furosemide Clonmel over a longer period of time, it is advisable to take additional vitamin B1 (thiamine) to compensate for its loss. Vitamin B1 supports cardiac function.

Exposure to sunlight or UV rays: inform your doctor if you experience an unusual skin reaction after exposure to sunlight or UV rays (photosensitivity), as it may be necessary to discontinue treatment.

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

If you are taking any of the following medicines **use with Furosemide Clonmel should be avoided**, if possible. Tell your doctor if you are taking any of the following:
- medicines which can cause ear or kidney damage - such as medicines to treat infections (medicines with active substance name beginning with "cef" (**cephalosporins**); **vancomycin, teicoplanin; kanamycin**, **gentamycin**, **tobramycin, polymyxins**), organoplatins (**cisplatin** used for the treatment of certain cancers) and other loop diuretics. If such combination is necessary the doctor will closely monitor your hearing function as well as kidney function, as necessary.
- **chloral hydrate**, a medicine to treat sleep disorders. Avoid taking Furosemide Clonmel while using chloral hydrate
- **lithium**, a medicine to treat depression and mental disorders. If the combination can not be avoided, your doctor will carefully monitor your lithium blood level.

The following medicines can affect or be affected by Furosemide Clonmel. Furosemide Clonmel **and these medicines should be used with caution**. Tell your doctor if you are taking any of the following as the doctor may need to adjust the dosage or take other precautions:
- **sucralfate**, a medicine to treat stomach and bowel ulcers. Do not take Furosemide Clonmel and sucralfate within 2 hours of each other.
- medicines to treat high blood pressure (**antihypertensives**), such as:
  - **ACE inhibitors** (medicines with active substance names ending in “pril”),
  - **angiotensin II receptor blockers** (medicines with active substance names ending in “sartan”) or
  - other antihypertensives (e.g. **aliskiren**), and
  - other medicines that increase urine output (**diuretics,** such as **amiloride, eplerenone, spironolactone, triamterene** etc.).
- alpha blockers for urological use (e.g. **doxazosin**, **prazosin, tamsulosin**)
- medicines used to treat depression (such as **imipramine**, selective serotonin reuptake inhibitors (**escitalopram**))
- certain medicines used to treat mood and behavioural disorders (**antipsychotics**) (such as chlorpromazine, levomepromazine, clozapine, quetiapine, amisulpride, tiapride, droperidol, haloperidol, pimozide, sertindole, flupentixol)
- **risperidone**, a medicine to treat mental disorders. Your doctor will very carefully assess the risks and benefits of simultaneous treatment with Furosemide Clonmel. This applies especially in elderly patients with dementia.
- **levothyroxine**, a medicine used to treat a thyroid hormone deficiency (hypothyroidism). Your doctor will monitor your thyroid hormone levels.
- medicines to treat inflammation and pain (NSAIDs), such as **acetylsalicylic acid** and **indomethacin**
- **phenytoin**, a medicine to treat epilepsy and certain pain conditions
- **oxcarbazepine**, **carbamazepine** (medicines to treat epilepsy)
- **baclofen,** a medicine used to treat involuntary muscle contractions
- medicines used for the treatment of heart problems such as **nitrates** and **cardiac glycosides** (e.g., **digitalis glycosides (digoxin)**)

- certain medicines used for heart rhythm disorders called **antiarrhythmics,** such as quinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide
- **certain antibiotics** in the macrolide family (e.g., spiramycin IV, erythromycin IV) or fluoroquinolones (e.g., moxifloxacin, levofloxacin), amphotericin B (IV)
- certain medicines that treat fungal or parasitic infections (e.g., **pentamidine**),
- certain medicines used to treat malaria (e.g. **halofantrine, lumefantrine**),
- certain medicines to treat constipation (e.g., **cisapride, prucalopride**),
- **vincamine IV** (a medicine used to treat minor neurological disorders)
- **methadone** (a medicine used to treat drug addiction)
- **carbenoxolone**, a medicine to treat gullet ulceration and inflammation
- **glucocorticoids**, medicines to treat inflammation or prevent organ transplant rejection, such as hydrocortisone, dexametazone etc.
- **tetracosactide** (hormone used for treatment of adrenal glands disorder)
- **aminoglutethimide** (a medicine to treat breast cancer or Cushing's syndrome)
- certain medicines used to treat cancer and its side effects (e.g. **amifostine, toremifene, arsenic trioxide and dolasetron IV**),
- **probenecid**, a medicine to treat gout
- **methotrexate**, a medicine to treat severe joint inflammation, cancer and psoriasis
- medicines to treat diabetes (including **metformin and desmopressin**)
- medicines used to increase blood pressure and slow heart rate in certain shock situations, such as **epinephrine, norepinephrine**
- **terfenadine** (a medicine to treat allergies)
- **theophylline**, a medicine to treat asthma and other breathing conditions
- some **muscle-relaxant medicines** with active substances ending in “curonium” or “curium”
- **ciclosporin A**, a medicine to suppress transplant rejection, treat severe skin diseases and severe eye or joint inflammation
- **contrast media**, substances used in X-ray procedures to image organs or vessels

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Furosemide Clonmel.

Furosemide Clonmel with food
Avoid large amounts of liquorice products when taking Furosemide Clonmel. Take Furosemide Clonmel on an empty stomach at least half an hour before a meal.

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.

Pregnancy
Only take Furosemide Clonmel during pregnancy if your doctor tells you it is absolutely necessary. If Furosemide Clonmel is taken during pregnancy, your doctor will carefully monitor:
- your electrolyte levels
- the percentage of blood cells in your blood
- the growth of your unborn child

Breast-feeding
Do not take Furosemide Clonmel if you are breast-feeding.

Driving and using machines
This medicine may make you feel dizzy and unwell. Do not drive or operate machinery if this happens.

Furosemide Clonmel 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.

Furosemide Clonmel contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Furosemide Clonmel

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

How to take
Take the tablets on an empty stomach at least half an hour before a meal, with one glass of water. Do not chew the tablet.
Furosemide Clonmel 40 mg tablets: The tablet can be divided into equal doses.

How much to take
The number of tablets you need will depend on your condition.

Adults
The recommended initial adult dose is 20-40 mg daily. The dose should be adjusted until the lowest effective dose is achieved. In some patients, daily doses of 80 mg or higher may be needed, depending on their condition. Your doctor will decide what is the appropriate dose for you.

Children and adolescents
The dose is determined according to body weight and calculated by the doctor. The recommended dose is from 1 to 2 mg per 1 kg of bodyweight.
For children not able to swallow the tablets other more suitable pharmaceutical forms containing furosemide may be on the market.

Elderly
Your doctor may need to adjust your dose of Furosemide Clonmel.

Patients with impaired liver function
Your doctor may adjust your dose if your liver function is moderately or severely impaired. See also section 2, "DO NOT take Furosemide Clonmel".

Patients with impaired kidney function
Your doctor may need to adjust your dose of Furosemide Clonmel. See also section 2, "DO NOT take Furosemide Clonmel".

Blood tests
Your doctor may carry out blood tests to check that the levels of some salts in your blood are at the correct levels.

If you take more Furosemide Clonmel than you should
If you or your child accidentally take too many tablets, tell your doctor immediately or contact your nearest hospital, even if there are no signs of discomfort. Take the medicine in its original packaging with you for the doctor to identify it easily.

Taking too much of Furosemide Clonmel may make you:
- feel confused, unable to focus, show a lack of emotion or interest in anything
- dizzy, lightheaded, feel faint
- experience uneven heartbeat, muscle weakness or cramps and clots (signs include pain and swelling at the part of body that is affected)
- may have problems with your kidneys or blood

If you forget to take Furosemide Clonmel
Do not take a double dose to make up for a forgotten dose. Take the forgotten dose as soon as possible on the same day or take the next dose as usual the next day.

If you stop taking Furosemide Clonmel
Do not stop taking Furosemide Clonmel without your doctor's permission, as this can seriously harm you and reduce the therapeutic effect.

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 this medicine and tell your doctor or go to your nearest emergency department immediately if you suffer from any of the following:
- **Severe allergic reaction** – signs may include hives, swelling of the face, lips, tongue or throat, difficulty breathing, cold clammy skin, pale skin colour and racing heartbeat (rare: may affect up to 1 in 1 000 people).
- **Inflammation of the pancreas** – causing severe stomach or back pain (very rare: may affect up to 1 in 10 000 people).
- **A low number of certain types of blood cells** – symptoms include bruising more easily (thrombocytopenia (uncommon: may affect up to 1 in 100 people)), getting more infections, sudden high fever, severe sore throat and ulcers in the mouth (leucopenia (rare: may affect up to 1 in 1 000 people) and/or agranulocytosis (very rare: may affect up to 1 in 10 000 people)), feeling weak or tired more than usual, pale skin, breathlessness, dark urine (haemolytic anaemia or aplastic anaemia (very rare: may affect up to 1 in 10 000 people)).
- **Dehydration or changes in levels of compounds normally present in your body (electrolyte disturbances)** – increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, upset stomach or irregular heartbeat could be experienced (very common: may affect more than 1 in 10 people).
- **Liver problems** – indicated by yellowing of the skin or eyes and dark-brown coloured urine (very rare: may affect up to 1 in 10 000 people).
- **Liver encephalopathy** – for patients who already have liver problems, a more serious liver problem that affects brain function may occur. Symptoms include forgetfulness, fits, mood changes and coma (common: may affect up to 1 in 10 people).
- **Serious skin reaction** (such as Stevens-Johnson syndrome, Toxic Epidermal Necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS) or acute generalised exanthematous pustulosis (AGEP)) – symptoms may include a widespread skin rash, blistering or peeling of the skin around the lips, eyes, mouth, nose, genitals or other parts of the body, flu-like symptoms and fever (frequency cannot be estimated from the available data).
- **Severe muscle degradation** – featuring unexplained muscle pain, tenderness or weakness (frequency cannot be estimated from the available data).
- **Kidney problem** – indicated by not going to the toilet (low urine output), nausea, tiredness, pain in your sides, swelling of your legs or blood in your urine (frequency cannot be estimated from the available data).

Other side effects can occur with the following frequencies:

Very common (may affect more than 1 in 10 people)
- reduced blood volume
- increased blood fat (triglyceride) concentration

- lower than normal blood pressure (hypotension), including orthostatic hypotension (causes circulation problems, especially when standing up, which may include going into shock in case of excessive diuresis)
- increased blood concentration of creatinine

Common (may affect up to 1 in 10 people)
- increased concentration of blood cells as a result of fluid loss
- reduced potassium, sodium and chloride levels in the blood
- increased blood concentrations of uric acid, gout
- increased blood fat (cholesterol) levels
- increased volume of urine

Uncommon (may affect up to 1 in 100 people)
- increased blood sugar levels
- hearing disorders, usually reversible, especially in patients with reduced kidney function or low protein levels in the blood (occurs in case of e.g. nephrotic syndrome)
- deafness (sometimes irreversible)
- allergic or non-allergic skin reactions
- nausea
- itching
- nettle-rash, skin rash
- severe inflammation of skin and mucous membrane, with signs such as blisters and fever (dermatitis bullous, erythema multiforme, bullous pemphigoid, dermatitis exfoliative)
- red or purple spots on the skin
- increased sensitivity to light

Rare (may affect up to 1 in 1 000 people)
- increased number of certain white blood cells known as eosinophilic granulocytes
- unusual tingling, prickling, burning or numb sensation
- ringing or buzzing in the ears (tinnitus)
- kidney inflammation
- inflammation of blood vessels
- vomiting, diarrhoea
- fever

Very rare (may affect up to 1 in 10 000 people)
- increased transaminase (liver enzyme) levels

Not known (frequency cannot be estimated from the available data)
- worsening or triggering of systemic lupus erythematosus (an inflammatory disease which causes joint pain, skin rashes and fever)
- reduced calcium or magnesium levels in the blood
- excessive alkaline levels in the blood, salt loss and low blood pressure due to a kidney disease (Pseudo-Bartter syndrome), related to misuse and/or long-term use of this medicine
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- headache
- blood clot which may block a blood vessel
- increased sodium or chloride levels in the urine
- increased blood concentration of urea
- urinary obstruction including acute urinary retention
- calcium salt deposits in kidney vessels and tissue and/or kidney stones in premature infants
- increased risk of the blood vessel connecting the lung artery and aortic arch not closing, if furosemide is given to premature infants during the first weeks of life
- rash that may occur on the skin or sores in the mouth (lichenoid reaction)

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:
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemide Clonmel

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 or blister /bottle label after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

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 Furosemide Clonmel contains

- The active substance is furosemide.
  Each Furosemide Clonmel 20 mg tablet contains 20 mg of furosemide.
  Each Furosemide Clonmel 40 mg tablet contains 40 mg of furosemide.

- The other ingredients are: lactose monohydrate, maize starch, pregelatinised maize starch, sodium starch glycolate (Type A), magnesium stearate.

What Furosemide Clonmel looks like and contents of the pack

Furosemide Clonmel 20 mg tablets are white to off-white, round tablets, 6 mm in diameter marked with F and 20 on one side.

Furosemide Clonmel 40 mg tablets are white to off-white, round tablets, 8 mm in diameter, marked with F and 40 on one side (F & 40 separated by break line).
Furosemide Clonmel 20 mg tablets is packed in:
PVDC/PVC//Alu blisters containing 30, 50, 100 tablets or
PVDC/PVC//Alu perforated unit dose blisters containing 30x1 tablet or
HDPE bottles with screw cap containing 100, 250, 500, 1000 tablets.

Furosemide Clonmel 40 mg tablets is packed in:
PVDC/PVC//Alu blisters containing 20, 30, 50, 100, 300 tablets or
PVDC/PVC//Alu perforated unit dose blisters containing 30x1, 50x1, 90x1,100x1 tablet and/or
HDPE bottles with screw cap containing 250, 500, 1000 tablets.

Not all pack sizes may be marketed.

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

Belgium:	Furosemide Eurogenerics 20 mg, 40 mg tabletten
Denmark:	Furosemide STADA
Finland:	Furosemide STADA 20 mg, 40 mg tabletit
Germany:	Furosemid AL 20 mg, 40 mg Tabletten
Iceland:	Furosemide STADA 20 mg, 40 mg töflur
Ireland:	Furosemide Clonmel 20 mg, 40 mg tablets
Luxembourg:	Furosemide Eurogenerics 20 mg, 40 mg comprimés
Malta:	Furosemide Clonmel 20 mg, 40 mg tablets
Netherlands:	Furosemide Centrafarm 20 mg, 40 mg, tabletten
Romania:	Furosemid STADA 20 mg, 40 mg comprimate
Slovenia:	Furosemid STADA 20 mg, 40 mg tablete

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