

PACKAGE LEAFLET – INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or your pharmacist. This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Diuresal®

40 mg Tablets (Furosemide)

1. What Diuresal Tablet is and what it is used for

What Diuresal Tablets are used for
Diuresal Tablets can be used to stop the buildup of extra water in your body. This extra water can cause swollen ankles, shortness of breath and feeling more tired than usual.

How Diuresal Tablets work

Diuresal Tablets work by helping you to pass more water (urine) than you usually do. If the extra water in your body is not removed, it can put extra strain on the heart, blood vessels, lungs, kidneys or liver.

2. Before you take Diuresal Tablets

Do not take Diuresal Tablets if:

- you are allergic (hypersensitive) to Furosemide and/or any of the other ingredients of Diuresal tablets (listed in section 6 below).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- you are allergic to amiloride, sulfonamides or sulphonamide derivatives, such as sulfadiazine or co-trimoxazole.
- you have been told by a doctor that you have kidney failure. In some types of kidney failure, it is still okay to have this medicine. Your doctor will be able to decide.
- you have severe liver problems (cirrhosis).
- your doctor has told you that you have a low blood volume or are dehydrated (with or without accompanying low blood pressure).
- you are not passing any water (urine).
- you have too little potassium or sodium in your blood (shown in blood test).
- you have an illness called 'Addison's Disease'. This can make you feel tired and weak
- you are breast-feeding (see "Pregnancy and breast-feeding" section below)
- you are taking other medicines which change the amount of potassium in your blood (see "Taking other medicines" section below)
- you are children and adolescents under 18 years of age. Diuresal tablets are not suitable for children.

Do not take Diuresal Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Diuresal Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Diuresal 40 mg Tablets if:

- you have low blood pressure or feel dizzy when you stand up.
- you are taking digoxin, used to treat heart problems
- you have diabetes
- 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
- you have difficulty in passing water (urine)
- you have low levels of protein in your blood (hypoproteinaemia)
- you suffer from acute porphyria symptoms of which may include severe stomach, back or thigh pain. Nausea, vomiting or constipation may also present along with weakness in arms and legs.
- you have liver or kidney problems
- you are an elderly patient with dementia and are also taking risperidone
- you have prostate problems
- you have gout
- you feel dizzy or dehydrated. This can happen if you have lost a lot of water through being sick, having diarrhoea or passing water very often. It can also happen if you are having trouble drinking or eating
- you are going to give this medicine to a baby that was born too early
- you are going to have a glucose test
- you are taking any other water tablets

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

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription, including herbal medicines.

This is because Diuresal tablets can affect the way some other medicines work. Also some medicines can affect the way Diuresal tablets work.

Do not take this medicine, and tell your doctor, if you are taking:

Medicines which change the amount of potassium in your blood. These include potassium supplements such as potassium chloride or certain water tablets (diuretics) such as triamterene.

The following medicines can affect the way Diuresal Tablets work and increase the chance of you getting side effects:

Medicines used to treat high blood pressure such as ramipril, enalapril, perindopril (called 'ACE inhibitors') or losartan, candesartan, irbesartan (called "angiotensin II receptor antagonists").

Your doctor may need to change the dose of your tablets or ask you to stop taking them.

Medicines for high blood pressure or heart problems. Your doctor may need to change the dose of your medicine.

Medicines used to treat high blood pressure or prostate problems known as alpha-blockers, such as prazosin. Other medicines used to treat high blood pressure and other medicines used to remove water from the body known as diuretics, such as amiloride, spironolactone, acetazolamide and metolazone.

Medicines used to treat unusual heart beats, such as amiodarone, disopyramide, flecainide, lidocaine, sotalol and mexiletine.

Medicines to help you sleep and relax such as chloral hydrate.

Medicines used as a general anaesthetic for relaxing your muscles during surgery.

If you are going to have an anaesthetic please ensure that the doctor or nurse knows you are taking furosemide

Medicines for diabetes - these may not work as well when you are taking Diuresal Tablets.

Theophylline - used for wheezing or difficulty in breathing.

Phenytoin - used for epilepsy. This can lower the effect of Diuresal Tablets.

Medicines used for mental problems called "psychoses", such as risperidone, amisulpride, sertindole, pimozide and chlorpromazine. Avoid using pimozide at the same time as furosemide.

The following medicines can increase the chance of side effects when taken with Diuresal Tablets:

Lithium - used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood.

Cisplatin - used for some cancers.

Digoxin - used for heart problems. Your doctor may need to change the dose of your medicine.

Non-steroidal anti-inflammatory drugs (NSAIDs) - used for pain and inflammation such as aspirin, ibuprofen, ketoprofen or indometacin.

Carbamazepine - used for epilepsy.

Aminoglutethimide - used for breast cancer.

Medicine used to stop the rejection of organs after a transplant such as tacrolimus, ciclosporin, adalimumab.

Moxislyte used to treat Raynaud's syndrome.

Medicines used to treat angina that you spray or dissolve under your tongue such as glyceryl trinitrate or isosorbide dinitrate.

Methotrexate - used for cancers of the skin, joint or bowel diseases.

Carbenoxolone and sucralfate - used for ulcers of the foodpipe (gullet).

Medicines used for depression, such as reboxetine, amitriptyline and phenelzine.

Amphotericin - used for fungal infections if used for a long time.

Corticosteroids - used for inflammation such as prednisolone

Atomoxetine used to treat Attention Deficit Hyperactivity Disorder (ADHD).

Medicines to relax muscles such as baclofen and tizanidine.

Antihistamines, used to treat allergies such as cetirizine.

Alprostadil, used to treat male impotence.

Oestrogen and drospirenone, used as contraceptives or in hormone replacement therapy (HRT).

Liquorice - often used in cough medicines if taken in large amounts

Probenecid (used with another HIV medicine).

Medicines for infection such as gentamicin, amikacin, neomycin, netilmicin, tobramycin, vancomycin or high doses of cephalosporins

Medicines used as injections before X-ray examinations (radiocontrast agent).

Medicines used for constipation (laxatives) if used for a long time such as bisacodyl or senna.

Medicines for asthma when given in high doses such as salbutamol, terbutaline sulphate, salmeterol, formoterol or bambuterol.

Medicines used to treat blocked noses, such as ephedrine and xylometazoline.

Potassium salts used to treat low potassium in the blood.

Medicines used to treat Parkinson's disease such as levodopa.

Other water tablets (diuretics) such as bendroflumethiazide. Your doctor may need to change the dose of your medicine.

Diuresal tablets with food, drink and alcohol: You should avoid drinking alcohol while taking Diuresal tablets as this may lower your blood pressure further.

Pregnancy and breast-feeding:

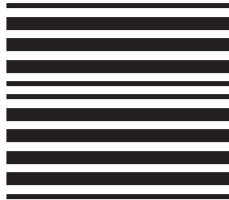
Do not take Diuresal Tablets if you are pregnant. Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you might be pregnant.

Do not breast-feed if you are taking Diuresal Tablets. This is because small amounts may pass into the mother's milk. Talk to your doctor before taking this medicine if you are breast-feeding or planning to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

Driving and using machines:

You may feel dizzy or unwell after taking Diuresal Tablets. If this happens, do not drive or use any tools or machines.



Important information about some of the ingredients of Diuresal Tablets

Diuresal Tablets contains lactose monohydrate. If your doctor has told you that you have an intolerance of certain sugars, contact your doctor or pharmacist before taking this medicine

3. How to take Diuresal Tablets

Always take Diuresal tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

Take this medicine by mouth.
Swallow the tablets whole with a drink of water.

If you are taking sucralfate (a medicine for stomach ulcers). Do not take sucralfate at the same time as Diuresal Tablets.

Take your dose at least 2 hours before or after Diuresal Tablets. This is because it can affect the way your medicine works.

If you take more Diuresal Tablets than you should:

If you think you may have taken more Diuresal Tablets than you should or if a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately.

Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets. Taking too much Diuresal Tablets may make you feel confused, unable to focus, show a lack of emotion or interest in anything. You may also have dizziness, light-headedness, fainting (due to low blood pressure), uneven heartbeat, muscle weakness or cramps and blood clots (signs include pain and swelling at the part of body that is affected). You may also have problems with your kidneys or blood.

If you forget to take Diuresal Tablets:

If you forget to take a dose, take it as soon as you remember. Then continue the following morning as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Diuresal Tablets:

Keep taking Diuresal tablets until your doctor tells you to stop taking it.

Blood tests

Your doctor may carry out blood tests to check that the levels of some salts in the blood are at the correct levels. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Diuresal Tablets can cause side effects, although not everybody gets them.

If any of the below mentioned side effects are observed please inform your doctor immediately allergic reactions such as itching, skin rash with severe itching and nettle rash, fever, allergic to light, severe allergic reaction with (high) fever, red patches on the skin, joint pain and/or inflammation of the eyes, severe, acute (allergic) reaction accompanied by fever and blisters on the skin/peeling skin and tiny spots from bleeding in the skin.

- sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back.

The other possible side effects are listed under headings of frequency, using the following categories:

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

Common

Diuresal can cause an excessive depletion of bodily fluids (e.g. passing urine more often than normal) and minerals (sodium, potassium, magnesium, calcium). Symptoms that can occur are thirst, headache, confusion, muscle cramps, increased irritability of the muscles, muscular weakness, heart rhythm disturbances and gastrointestinal problems such as sensation of unease and discomfort in stomach with an urge to vomit, or diarrhoea.

If you have a shortage of magnesium and calcium (magnesium and calcium deficiency):

increased irritability of the muscles, heart rhythm disturbances, lowering of blood pressure, resulting in impaired concentration and reactions, light-headedness, a feeling of pressure in the head, headache, dizziness, drowsiness, a feeling of weakness, visual disturbances, dry mouth and an inability to stand upright.

Uncommon

Abnormal blood count accompanied by bruising and a tendency to bleed, sensitivity to light, (photosensitivity), involuntary leakage of urine, in the elderly, this can lead to a low blood volume, fluid depletion and thickening of the blood. This can cause clots to form in the blood. Deafness (sometimes irreversible)

Rare

Abnormal blood count (white blood cell deficiency) accompanied by a increased susceptibility to infection, increase in certain substances (eosinophilic cells) in the blood, a crawling sensation on the skin, itching or tingling without any reason, a life-threatening form of unconsciousness, hearing disorders & ringing in the ears. These disorders are usually temporary in nature: inflammation of a blood vessel, acute kidney failure, inflammation of the kidneys associated with blood in the urine, fever and pain in the sides.

If you have a urinary tract obstruction, increased urine production may occur or worsen.

If you have a bladder disorder, enlarged prostate or narrowing of the ureters, urine production can stop suddenly, shock (severe drop in blood pressure, extreme paleness, restlessness, weak fast pulse, clammy skin, impaired consciousness) as a result of a sudden severe dilatation of the blood vessels due to allergy to certain substances, fever, minor mental disturbances.

Very rare

Anaemia (a condition characterised by shortage of red blood cells), very severe blood abnormality (white blood cell deficiency) such accompanied by a sudden high fever, severe throat pain and ulcers in the mouth, certain liver function disorders, increase in certain liver enzymes

Not known:

Acute generalised exanthematous pustulosis (AGEP)* (acute febrile drug eruption), dizziness, fainting and loss of consciousness (caused by symptomatic hypotension). During treatment with furosemide, the blood levels of some fats (cholesterol and triglyceride) may rise, but usually return to normal within 6 months.

5. How to store Diuresal Tablets?

Keep out of the reach and sight of children.
Store the tablets in a cool and dry place (15°-25°C). Keep the container tightly closed. Keep the container in the outer carton.

Do not use your tablets after the expiry date stated on the carton or label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Diuresal Tablets contains:

The active substance is Furosemide.

What Diuresal Tablets look like and content of the pack:

Diuresal tablets 40 mg are white-to off white, flat, uncoated tablets with a score line on one side and the embossed Furosemide 40 on the other side.

Diuresal tablets are available in container packs of 24.

Marketing Authorisation Holder and Manufacturer
Pharmaceuticals Lagap SA, Switzerland

This leaflet was last approved in **02/2016**.

INSTRUCTIONS TO THE PATIENT
This is a Medicament
- Medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you. - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. - The doctor and pharmacists are experts in medicine, its benefits and risks.- Do not by yourself interrupt the period of treatment prescribed for you. - Do not repeat the same prescription without consulting your doctor.
KEEP MEDICAMENT OUT OF THE REACH OF CHILDREN

Information updated: February 2016
Council Of Arab Health Ministers
Union of Arab Pharmacists