

Frusol® 50mg/5ml Oral Solution 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 Frusol is and what it is used for
2. What you need to know before you take Frusol
3. How to take Frusol
4. Possible side effects
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1. What Frusol is and what it is used for

The name of your medicine is Frusol 50mg/5ml Oral Solution (called Frusol in this leaflet). It contains furosemide. This belongs to a group of medicines called diuretics, or water tablets.

Furosemide can be used to remove the levels of excess water in the body caused by heart, lung, kidney, liver or blood vessel problems.

2. What you need to know before you take Frusol

Do not take Frusol and tell your doctor if:

- you are allergic (hypersensitive) to furosemide, sulphonamides or any other ingredients in this liquid (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- you have symptoms of weakness, difficulty in breathing and light-headedness. This could be a sign of having too little water in the body
- you are dehydrated
- you are not passing water (urine) at all or only a small amount each day
- you have kidney failure or liver problems, including cirrhosis or liver encephalopathy (confusion, altered levels of consciousness and coma as a result of liver failure)
- you have a severe change in blood salts, such as high potassium or calcium levels or low sodium or magnesium levels. You may notice signs of this such as muscle cramps, weakness and tiredness. You must **not** take other medicines or supplements that contain potassium
- you have low blood pressure. The signs of this include dizziness, feeling less alert than usual, fainting and general weakness
- you have an illness called 'Addison's disease'. This is when your adrenal glands are not working properly. It can cause weakness, tiredness, weight loss and low blood pressure
- you are taking digoxin, used to treat heart problems
- you are breast-feeding.

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

Warnings and precautions

Talk to your doctor before taking Frusol, if:

- you have difficulty in passing water (urine), particularly if you have an enlarged prostate gland
- you have gout
- you have low levels of protein in the blood. The signs of this may include swelling, feeling sick (nausea) or being sick (vomiting), diarrhoea and stomach pain
- you have liver congestion (slowed blood flow through the vessels) or other liver problems
- you have kidney problems
- you have brain disorders affecting your nervous system, or a condition called porphyria. This is a disorder that can cause skin blisters, pain in and around the stomach area (abdomen)
- you have diabetes
- you are going to give this medicine to a baby that was born too early
- you have an abnormal heart rhythm or have a history of heart problems
- you are elderly (above 65), especially if you are taking risperidone for dementia
- you are pregnant
- if you are elderly, if you are taking any other medication that can cause a drop in blood pressure or if you have any medical conditions that can cause a drop in blood pressure.

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

Having operations and tests whilst on Frusol

Tell your doctor, dentist or nurse you are taking this medicine if

- you are going to have an anaesthetic
- you are going to have an X-ray examination that involves taking medicines before the procedure.

While you are taking this medicine, your doctor may give you regular blood tests. Your doctor will do this to monitor levels of salts, minerals and glucose in your blood and to check that your kidneys are working properly.

Other medicines and Frusol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because furosemide, the main ingredient of this medicine, can affect the way some other medicines work. Also some medicines can affect the way furosemide works.

Your doctor may need to change your dose and/or to take other precautions if you are taking one of the following medicines:

- Aliskiren – used to treat high blood pressure

Tell your doctor if you are taking any of these medicines:

- medicines used to treat high blood pressure known as ACE-inhibitors or Angiotensin-II receptor antagonists, such as captopril and losartan or hydralazine
- medicines used to treat high blood pressure or prostate problems known as alpha-blockers, such as prazosin
- 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 used to treat angina that you spray or dissolve under your tongue such as glyceryl trinitrate or isosorbide dinitrate
- warfarin, used to prevent atrial fibrillation, unwanted clotting and stroke
- medicines used to treat high cholesterol, such as clofibrate, colestyramine or colestipol
- moxislyte used to treat Raynaud's syndrome
- medicines used to treat pain and inflammation known as NSAIDs, such as indometacin or salicylates such as aspirin
- medicines used to treat inflammation known as corticosteroids, such as prednisolone and dexamethasone
- medicines used to treat infections caused by bacteria, such as tetracyclines (including tetracycline, oxytetracycline, minocycline, doxycycline, lymecycline) vancomycin, gentamicin, trimethoprim, cephaloridine, ceftriaxone and colistin
- medicines used to treat infections caused by fungus, such as amphotericin
- medicines used to treat infections caused by a virus, such as nelfinavir, ritonavir and saquinavir
- drugs used after transplants, such as tacrolimus, ciclosporin, aldesleukin
- medicines used for depression, such as reboxetine, amitriptyline and phenelzine
- medicines used for mental problems called 'psychoses', such as risperidone (see section 'Do not take Frusol'), amisulpride, sertindole, pimozide and chlorpromazine. Avoid using pimozide at the same time as furosemide
- lithium, used to treat extreme mood swings
- medicines used to help you sleep, such as chloral hydrate and triclofos
- atomoxetine used to treat Attention Deficit Hyperactivity Disorder (ADHD)
- medicines used to treat epilepsy, such as carbamazepine, phenobarbital and phenytoin
- medicines used to treat Parkinson's disease such as levodopa
- medicines used to treat diabetes, including insulin
- medicines to treat asthma, such as salmeterol, salbutamol and theophylline. These medicines also treat chronic obstructive pulmonary disease
- medicines used to treat blocked noses, such as ephedrine and xylometazoline
- medicines used to treat cancer such as cisplatin, methotrexate and aminoglutethimide
- medicines to relax muscles such as baclofen and tizanidine
- laxatives that help you go to the toilet
- alprostadil, used to treat male impotence
- oestrogen and drospirenone, used as contraceptives or in hormone replacement therapy (HRT)
- probenecid, used to treat gout
- potassium salts used to treat low potassium in the blood
- sucralfate, used to treat stomach ulcers. Do not take sucralfate within two hours of taking Frusol. This is because the sucralfate can stop the Frusol from working properly
- antihistamines, used to treat allergies such as cetirizine
- medicines or food containing liquorice.

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

Frusol with food, drink and alcohol

You should avoid drinking alcohol while taking Frusol as this may lower your blood pressure further.

Pregnancy and breast-feeding

If you are pregnant, 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 this medicine if you are breast-feeding.

Driving and using machines

While taking this medicine you may feel less alert than normal. If this happens, do not drive a car or use any tools or machines.

Frusol contains ethanol (10%v/v), liquid maltitol and propylene glycol:

- ethanol (Alcohol) – This medicine contains 79.5 mg of alcohol (ethanol) in each ml. The amount in 5ml of this medicine is equivalent to less than 10 ml beer or 4 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.
- liquid maltitol (E 965) – If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

- propylene glycol (E1520) – This medicine contains 0.35 mg propylene glycol in each 5ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.
- This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially ‘sodium-free’.

3. How to take Frusol

Always take this medicine exactly as your doctor or pharmacist has told you. Look on the label and check with your doctor or pharmacist if you are not sure.

Taking this medicine

- this medicine contains 50mg of furosemide in each 5ml
- take this medicine by mouth
- this medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes:
 1. ensure the tube is clear before taking the medicine
 2. flush the tube with a minimum of 5mL of water
 3. administer the medicine gently and slowly into the tube, with a suitable measuring device
 4. flush the tube again with a minimum of 5mL of water.

A 10mL flush volume should be used for large bore size tubes (18 Fr).
- it is best to take your dose in the morning
- plan your doses so that they do not affect your personal activities and sleep
- ask your doctor or pharmacist to help you plan the best time to take this medicine.

Adults

The usual dose for adults is:

- 40mg each day
- take the dose prescribed by your doctor.

Use in children

The usual dose for children is:

- 1mg to 3mg for each kilogram of the child’s body weight
- the correct dose will be worked out by the doctor
- children should not take more than 40mg each day.

Older People

If you are an older person, your doctor may start you on a lower dose and gradually raise this dose.

If you take more Frusol than you should

If you take more of the medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Frusol

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

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.

If you have any of the following side effects while taking your medicine tell your doctor immediately or go to hospital straight away:

- severe allergic reaction which may include a skin rash, itching, dermatitis, peeling skin, sensitivity to sunlight or sun lamps or fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing
- inflammation of blood vessels (vasculitis, which may cause rash, fever and joint or muscle pains) or kidney inflammation, this may change the number of times you pass urine or you may see blood in your urine. You may have a fever, feel drowsy, or notice swelling e.g. of the ankles
- blood clot (causing pain, swelling or tenderness in the legs).

If you get any of the following side effects, see your doctor as soon as possible:

Very common: may affect more than 1 in 10 people

- dehydration
- altered balance of fluid or chemicals in the body (e.g. sodium, potassium, chlorine, calcium and magnesium) causing a dry mouth, weakness, tiredness or drowsiness, restlessness, fits, muscle pain fatigue or cramps, low pressure causing loss of concentration and slowed reactions, difficulty passing water, fast or irregular heart rate and feeling and being sick.

Common: may affect up to 1 in 10 people

- low blood volume (hypovolaemia)
- increased creatinine and blood urea (seen in blood tests).

Uncommon: may affect up to 1 in 100 people

- anaemia causing tiredness, breathlessness, unusual bleeding or bruising
- changes in the body seen in tests such as levels of cholesterol, glucose, uric acid
- gout
- changes in vision including blurred or yellow vision
- light-headedness, sensations of pressure in the head, headache, drowsiness, weakness, changes in vision, dry mouth, dizziness when standing.
- irregular heartbeat
- muscle cramps or weakness
- changes in the amount or need to urinate
- tiredness
- dry mouth, thirst
- feeling or being sick
- changes in bowel movements including diarrhoea and constipation
- deafness (sometimes irreversible).

Rare: may affect up to 1 in 1,000 people

- changes in blood cells such as amount of white blood cells, reduction of platelets causing a rash fever, sweating, tiredness, and weight loss. Your doctor will perform regular blood tests to ensure no changes have occurred
- psychiatric disorder NOC causing delusions, hallucinations, disorganized speech
- feeling 'pins and needles' or tingling sensation
- confusion
- headache
- 'ringing' in the ears, loss of hearing usually reversible
- symptoms of shock such as changes in heart rate, breathlessness, cool clammy skin
- inflammation of the pancreas causing pains in your abdomen or back and nausea
- changes in the liver causing yellowing of the skin or whites of the eyes
- skin rashes
- tiredness, generally feeling unwell
- fever
- acute kidney failure
- kidney damage (interstitial nephritis).

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

- involuntary movements of the muscle
- inflammation or failure of the kidney which may cause back pain or changes in the amount or need to urinate.

Not known: frequency cannot be estimated from the available data

- worsening of conditions where there is already balances of fluid or chemicals in the body
- acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- decreased levels of potassium in the body.

This medicine may raise cholesterol and lipid (fat) levels in the blood.

If this medicine is used in babies born too soon (prematurely), this medicine can cause:

- persistence of a blood channel that normally closes at or around birth. This may cause heart failure, failure to grow, shortness of breath and rapid pulse
- kidney stones and/or calcium deposits in the body.

Tell your doctor if you get any of these side effects:

- feeling sick (nausea) or being sick (vomiting)
- generally feeling unwell.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Yellow Card Scheme www.mhra.gov.uk/Yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Frusol

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- After you open the bottle, this medicine expires after 3 months. Take this medicine back to the pharmacy three months after you first open it.
- Do not use this medicine after the expiry date which is stated on the label and carton (exp: month, year). The expiry date refers to the last day of that month.
- Do not use Frusol if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist.
- 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 Frusol 50mg/5ml Oral Solution contains

- The active substance is furosemide.
- The other ingredients are ethanol, sodium hydroxide, cherry flavour (containing ethanol and propylene glycol (E1520)), liquid maltitol (E965), disodium hydrogen phosphate (E339), citric acid monohydrate (E330), and purified water.

What Frusol 50mg/5ml Oral Solution looks like and contents of the pack

A clear colourless to straw coloured liquid that smells like cherry.

It comes in a brown glass bottle holding 150ml of solution.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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