



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FRUMED INJECTION

Furosemide 20mg/2ml Injection

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Frumed Injection is and what it is used for
2. What you need to know before you are given Frumed Injection
3. How to take Frumed Injection
4. Possible side effects
5. How to store Frumed Injection
6. Contents of the pack and other information

1. WHAT FRUMED INJECTION IS AND WHAT IT IS USED FOR

Frumed Injection contains the active ingredient Furosemide. Furosemide is a member of a group of medicines called diuretics. Furosemide works by helping to produce more urine. This helps to relieve symptoms caused when your body contains too much fluid.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN FRUMED INJECTION

Do not use Frumed Injection if:

- You are allergic (hypersensitive) to Furosemide, or any of the other ingredients of this medicine.
- You are allergic to sulphonamide antibiotics.
- You are severely dehydrated (you have lost lots of body fluid for example by suffering from severe diarrhoea or being sick)
- You have kidney failure and are not producing urine, despite treatment with furosemide.
- You have kidney failure because of poisoning with kidney or liver toxic substances.
- You have very low levels of potassium or sodium in your blood.
- You are breastfeeding.

If you are uncertain whether you can use this medicine or not, ask your doctor or pharmacist.

Take special care with FRUMED INJECTION if:

- You normally have problems passing water due to an obstruction (such as an enlarged prostate)
- You have diabetes.
- You have low blood pressure or sometimes have sudden falls in blood pressure (your blood vessels in your heart or brain are too narrow).
- You have liver disease (such as cirrhosis)
- You have kidney problems (such as nephrotic syndrome)
- You are dehydrated (you have lost body fluids by suffering from severe diarrhoea or being sick), this might lead to a collapse or blood clotting.



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- You have gout (painful or inflamed joints) due to high levels of uric acid (a by-product of metabolism) in your blood.
- You have an inflammatory disease called “systemic lupus erythematosus (SLE)”
- You have hearing problems.
- You are using sorbitol (sugar substitute for people with diabetes)
- You have porphyria (disease where the production of the oxygen binding molecule of the red blood cells is disrupted and urine is purple-coloured).
- Your skin has an increased sensitivity to sunlight (photosensitivity)
- If you are elderly, if you are on other medications which can cause a drop in blood pressure and if you have other medical conditions that are risks for the drop of blood pressure.
- If given to premature babies, furosemide can cause kidney stones or calcification.
- If any of these applies to you, your doctor may want to change your treatment or give you special advice. Your doctor may recommend regular tests of your blood sugar levels or your blood uric acid levels. They will also check your blood levels for important body salts such as potassium and sodium, which are particularly important if you are sick or have diarrhoea.

Taking other medicines with FRUMED INJECTION

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines you have obtained without a prescription. This is important because some medicines should not be taken together with furosemide solution for injection or Infusion.

Tell your doctor or pharmacist if you are taking:

- **Lithium:** for mood disorders, as its effect and side effects may be increased by furosemide. Your doctor will prescribe this medicine to you only if necessary and he will then check your lithium levels and may change your dose.
- **Heart medicines**, such as digoxin; your doctor may need to change your dose.
- **Any medicines for high blood pressure**, including thiazide diuretics (such as bendroflumethiazide or hydrochlorothiazide), ACE inhibitors (such as lisinopril), angiotensin II antagonists (such as losartan), as furosemide may cause your blood pressure to fall too low. Your doctor may need to change your dose of furosemide.
- **Cholesterol or lipid-lowering medicines** such as colestyramine, colestipol and fibrates, such as clofibrate, as the effect of furosemide may be reduced.
- **Diabetes medicines**, such as metformin and insulin, as your sugar levels may be increased.
- **Anti-inflammatory medicines**, including NSAIDS (such as aspirin or celecoxib), as they can reduce the effects of furosemide; high doses of pain killers (salicylates) may increase the side effects of furosemide.
- **Anti-inflammatory or anti-allergic medicines** such as corticosteroids, medicines used to treat stomach ulcers such as carbenoxolone, or laxatives, as in combination with furosemide they will affect your sodium and potassium levels. Your doctor will check your potassium levels.
- **Injections given during operations**, including tubocurarine, curarine derivatives and succinylcholine.
- **Chloral hydrate:** for sleeping problems (in isolated cases, the intravenous administration [injection into a vein] of furosemide in a 24-hour period prior to chloral hydrate administration



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may lead to flushing, increased sweating, anxiety, nausea, increase in blood pressure and faster heartbeat). Therefore, the simultaneous administration of furosemide and chloral hydrate is not recommended.

- **Phenytoin or Phenobarbital:** for epilepsy, as the effect of furosemide may be decreased.
- **Theophylline:** for asthma, as its effect may be increased by furosemide. Antibiotics such as cephalosporins, polymyxins, aminoglycosides or quinolones or other drugs which may affect your kidneys such as immunosuppressants, iodinated contrast media, foscarnet or pentamidine as furosemide can make this worse
- **Probenecid:** used with some other medicines to protect the kidney, as it may reduce the effects of furosemide
- **Organoplatins:** used in some cancers, as furosemide may increase the side effects of this drug.
- **Methotrexate:** used in some cancers and for severe arthritis, as it may reduce the effects of furosemide - Drugs to raise your blood pressure (pressor amines), as they may not work as well when you take them with furosemide
- **Aminoglutethimide:** used to suppress corticosteroid production (Cushing's syndrome), as it may increase the side effects of furosemide.
- **Carbamazepine:** used to treat epilepsy or schizophrenia, as it may increase the side effects of furosemide
- **Sucralfate:** used to treat stomach ulcers. Do not take furosemide within two hours of taking sucralfate as the effect of furosemide will be decreased.
- **Ciclosporin:** used to prevent rejection of transplants, as you are at risk of gouty arthritis (painful joints) - Drugs that alter your heartbeat such as amiodarone, sotalol, dofetilide and ibutilide as their effects may be increased by furosemide.
- **Risperidone:** used for the treatment of mental disorders

Pregnancy

Furosemide should not be used during pregnancy unless there are very good medical reasons for using it.

Breast-feeding

Furosemide gets into breast milk, and you must not breastfeed while taking it. If you are pregnant or if you are breastfeeding, ask your doctor or pharmacist for further advice before taking furosemide or any other medicine.

Driving and using machines

Do not drive or operate machinery as furosemide may reduce mental alertness.

3. HOW TO TAKE FRUMED INJECTION

Frumed Injection is given:

- As a slow injection into a vein (intravenous).
- In exceptions, into a muscle (intramuscular), your doctor will decide how much you need, when it is to be given to you and the duration of treatment. This will depend on your age, weight, medical history, any other medicines that you are taking and the type and severity



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of your disease.

General:

- The parenteral administration of furosemide is indicated in cases where oral administration is not feasible is not efficient (for example in case of reduced intestinal absorption) or when a quick effect is required.
- In cases where parenteral administration is used, the switch to oral administration is recommended, as soon as possible.
- To achieve optimum efficacy and suppress counter-regulation, a continuous furosemide infusion is generally preferred to repeated bolus injections.
- Where continuous furosemide infusion is not feasible for follow-up treatment after one or several acute bolus doses, a follow-up regimen with low doses given at short intervals (approx. 4 hours) is to be preferred to a regimen with higher bolus doses at longer intervals.
- Intravenous furosemide must be injected or infused slowly; a rate of 4 mg per minute must not be exceeded and should never be given in association with other medicinal products in the same syringe dosage regimen.

Adults

- In the absence of conditions requiring a reduced dose (see below) the initial dose recommended for adults and adolescents over 15 years, is of 20 mg to 40 mg furosemide (1 or 2 ampules) by intravenous (or in exceptional cases intramuscular) administration; the maximum dose varying according to individual response.
- If larger doses are required, they should be given by 20 mg increments and not given more often than every two hours.
- In adults, the recommended maximum daily dose of furosemide administration is 1500 mg.
- Larger initial or maintenance doses may be needed in certain circumstances, depending on your medical condition. This will be determined by your doctor. If such doses are needed, they may be given by continuous infusion. Children and adolescents (up to 18 years of age):
- The experience in children and adolescents are limited. The intravenous administration of furosemide to children and adolescents below 15 years is only recommended in exceptional cases.
- The dosage will be adapted to the body weight, and the recommended dose ranges from 0.5 to 1 mg/kg body weight daily up to a maximum total daily dose of 20 mg. There should be a switch to oral therapy as soon as possible.

Renal impairment

- In patients with severe impairment of renal function (serum creatinine > 5 mg/dl) it is recommended that an infusion rate of 2.5 mg furosemide per minute is not exceed.

Elderly

The recommended initial dose is 20 mg/day, increasing gradually until the required response is achieved.

If you miss a dose of furosemide solution for injection or infusion

- If you are concerned that you may have missed a dose, talk to your doctor or other medicinal



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staff immediately.

If you receive more furosemide solution for injection or infusion than you should

- If you are concerned that you may have been given too much furosemide, talk to your doctor or other medicinal staff immediately. Signs which may occur if you have been given too much of this medicine are dryness of the mouth, increased thirst, irregular heartbeat, mood changes, muscle cramps or pain, feeling or being sick, unusual tiredness or weakness, a weak pulse or loss of appetite.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Furosemide can cause side effects, although not everybody gets them. If you notice any of the following, tell the doctor or nurse immediately:

Uncommon (may affect up to 1 in 100 people)

- Skin rashes (including itching, redness, peeling), a bruising tendency or your skin being sensitive to sunlight.
- Blood cell changes can lead to failure of blood clotting (with increased risk of bleeding).
- Deafness (sometimes irreversible).

Rare (may affect up to 1 in 1,000 people)

- Feeling or being sick, diarrhoea, constipation, loss of appetite, discomfort in the mouth and stomach.
- Hearing problems (more common in kidney failure) and tinnitus (ringing in the ears).
- Anaphylaxis, a severe allergic reaction which can cause skin rashes, swelling, breathing difficulties, and loss of consciousness. Seek medical help immediately.
- Kidney damage (interstitial nephritis)
- Very low white blood cell levels in the blood (which can lead to life threatening infections).
- Muscle problems, including leg cramps or muscle weakness.
- Pain or discomfort where the injection is given (particularly after injection into muscle).
- The inflammatory disease lupus erythematosus may occur or get worse.
- Changes in blood test results (fat-like substances in your blood).
- A numb feeling, tingling, or feeling dizzy.
- High temperature.
- Blurred eyesight, confusion, sleepiness.
- Dry mouth

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

- Severe muscle problems including twitching, spasms, cramps (also called "tetanus").
- Blood cell changes that can lead to anaemia, inability to fight infection.
- Pancreatitis (severe tummy pain) due to inflammation of the pancreas.

Not known (frequency cannot be estimated from the available data) acute generalized exanthematous pustulosis (AGEP)" (acute febrile drug eruption)

- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)



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Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FRUMED INJECTION

- Keep all medicines out of the reach of children.
- Store below 30° C.
- Do not use after the expiry date which is stated as 'Exp. Date' on the ampoule and carton. The expiry date refers to the last day of that month.

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

6. FURTHER INFORMATION

What Frumed Injection contains

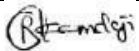


The active ingredient of Frumed Injection is Furosemide. Each 2ml contains 20 mg of the active ingredient.

What Frumed Injection looks like and contents of the pack

10x2ml ampoule placed in a carton with patient information leaflet.

MANUFACTURER

Fidson Healthcare Plc,
 Km.38, Lagos-Abeokuta Expressway,
 Sango-Ota, Ogun State, Nigeria
 234-(0)8077008888
 customercare@fidson.com

	Prepared by	Approved by	
Signature			
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