

PACKAGE LEAFLET: INFORMATION FOR THE USER

Frusene Tablets (Furosemide and triamterene)

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.

In this leaflet:

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

1. What Frusene is and what it is used for

The active ingredients of Frusene belong to a group of medicines known as diuretics. They work on your kidneys to get rid of excess water from the body. You may have gone to your doctor with problems such as swollen ankles or feeling breathless. These and other symptoms often occur because there is excess water in your body.

- You have been prescribed these tablets to help get rid of this excess water and you will notice that you pass more urine soon after you take your tablets.

2. What you need to know before you take Frusene

Do not take Frusene if:

- you are allergic (hypersensitive) to furosemide, triamterene or any of the other ingredients of this medicine (listed in section 6)
- you are allergic to sulfonamides, a type of antibiotic
- you have kidney or serious liver problems
- you have been told that you have high levels of potassium or low sodium in your blood.

Warnings and precautions

Talk to your doctor or pharmacist before taking Frusene if:

- you have a folic acid deficiency
- you have an enlarged prostate (hyperplasia of the prostate)

- you have or think you have dementia
- you are taking any type of NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) such as Ibuprofen or diclofenac
- you have or have had any kidney or liver problems (including elderly patients) as you may have to be closely monitored by your doctor.
- you are diabetic
- you have had a heart attack and/or have fluid in the lungs (pulmonary oedema)
- you are taking other medicines for your heart or your blood pressure. Your doctor may decide to alter the amount of the dose of these once you start taking Frusene
- you have difficulty passing urine
- you have been told by your doctor that you have an intolerance to some sugars.
- 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.

Children

Do not give this medicine to children

Blood Tests

Your doctor will need to check your blood tests regularly.

Other medicines and Frusene

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

In particular, tell your doctor if you are taking any of the following:

- other diuretic agents such as amiloride, spironolactone
- drugs used to treat high blood pressure and heart conditions such as beta blockers, digoxin, sotalol, ACE inhibitors, angiotensin receptor blockers, calcium-channel blockers and diuretics. If you have any questions ask your doctor or pharmacist.
- drugs used to treat low blood pressure
- potassium supplements or drugs that alter the body's potassium or sodium levels
- muscle relaxants
- antibiotics (trimethoprim) and the antiviral drug amantadine
- immunosuppressants such as ciclosporin
- drugs used to treat diabetes
- drugs used to treat dementia such as risperidone
- lithium salts
- lipid lowering drugs (Cholestyramine,cholestipol, clofibrate)
- antiepileptic agents such as phenobarbitol, phenytoin and carbamazepine
- anti-inflammatory drugs including corticosteroids and NSAIDs such as ibuprofen

- drugs that alter your kidney function such as aminoglycoside, cephalosporin antibiotics, amphotericin B and NSAIDs
- drugs that alter your hearing such as aminoglycoside antibiotics, cisplatin
- drugs that alter your hormones including the contraceptive pill and some anticancer medications.
- drugs used to treat asthma (theophylline).

Patients should note that smoking tobacco can reduce the effect of Frusene.

Frusene with food and drink

Take Frusene Tablets with a glass of water on an empty stomach. See Section 3.

Large amounts of glycyrrhizin which is contained in liquorice can affect how well Frusene works. If you are unsure ask your doctor or pharmacist for advice.

Pregnancy and breast-feeding

It is not recommended that you take Frusene whilst you are pregnant or breast-feeding. Your doctor will decide if the benefits outweigh the risks.

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

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

At the start of therapy some patients may experience dizziness or vertigo. If this occurs then you should not drive or use machinery.

Frusene 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.

3. How to take Frusene

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

For adults and older people:

- The usual dose is ½ to 2 tablets in the morning, but your doctor may have told you to take more than this.
- Do not take more than 6 tablets per day.
- The tablets have a score line which will help you to cut them in half if this is necessary.
- Take Frusene Tablets with a glass of water on an empty stomach.
- You will find that you have the urge to pass water soon after taking your Frusene. Because of this it is better to take your tablet(s) first thing in the

morning, so that you pass any extra water early in the day, leaving you free to go about your usual routine, undisturbed. If your work is at night, it will be better for you to take your tablets in the evening.

Children

Frusene is not recommended for use in children.

Patients with Liver or Kidney Problems

Your doctor may start your treatment at lower doses and monitor you very closely before increasing the dosage.

If you take more Frusene than you should

If you accidentally take too much Frusene, you may get rid of too much water and become dehydrated. You may notice this by feeling dizzy or having muscle cramps. If this happens, drink plenty of water and see your doctor as soon as possible.

If you forget to take Frusene

If you forget to take your usual dose, take it as soon as you remember, then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Frusene

Do not stop taking this medicine without telling your doctor first. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

Serious side effects

If you experience any of the following side effects, contact your doctor or go to your nearest hospital casualty department **immediately**:

- Blistering of the skin with or without blistering of mouth, eyes or genitals
- Skin rashes including red, raised, lumpy, itchy or spotty rash
- Difficulty breathing

Other side effects

If you experience any of the side effects in the lists below, contact your doctor

Very common (seen in more than 1 in 100 patients)

- Dry mouth and feeling thirsty (dehydration)
- Changes in blood levels of minerals (sodium, potassium, calcium, magnesium) which can cause tiredness and confusion, muscle twitching, fits and coma
- Lowered blood pressure

- Feeling sick or being sick
- Diarrhoea
- Sometimes your urine may look slightly blue in colour; this is nothing to worry about.

Uncommon (seen in between 1 in 100 and 1 in 1000 patients)

- High levels of uric acid in the blood and gout which may cause swollen and painful joints
- Changes in blood cholesterol and triglyceride levels
- Low blood volume which may make you feel light headed
- Bladder problems such as loss of control, being unable to urinate or changes in frequency
- Changes in bowel movements
- Changes in kidney function and higher levels of creatinine in the blood
- Muscle cramps
- Dizziness
- Pins and needles
- Restlessness, tiredness or headache
- Problems with your sight
- Irregular heartbeat
- Low blood pressure
- Changes to blood sugar levels
- Unexpected bruising
- Deafness (sometimes irreversible)

Rare (seen in less than 1 in 1000 patients)

- Problems with your immune system and red blood cells which can cause weakness, pale skin, breathlessness, bruising or make infections more likely
- Loss of hearing or ringing in your ears
- Liver and kidney problems and pancreatitis
- Kidney stones
- Increased sensitivity to sunlight
- High temperature
- Weakness

Frequency not known

- Reduction in white blood cells
- High levels of calcium in urine
- Hearing loss caused by problems in inner ear or nerves
- Acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)

Effects on newborn (especially premature) babies

- Closure of the patent arterial duct may be hindered after birth

- Reduced kidney function and blood in the urine (Nephrocalcinosis)

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 at: 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 Frusene

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 blister strip and on the container. The expiry date refers to the last day of that month.
- Store the tablets in their original container.
- Do not store above 25°C.

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 to protect the environment.

6. Contents of the pack and other information

What Frusene contains

- The active substances are furosemide (40 mg) and triamterene (50 mg).
- The other ingredients are lactose, maize starch, pregelatinised starch, gelatin, polysorbate 80, sodium starch glycolate and magnesium stearate.

What Frusene looks like and contents of the pack

Frusene tablets are round pale-yellowish tablets and are available in blister strips of 14 tablets. Your doctor will decide how many tablets to prescribe for you.

Marketing Authorisation Holder

Orion Corporation, Orionintie 1,
FIN-02200 Espoo, Finland.

Manufacturer

Orion Corporation,
Orion Pharma,
Orionintie 1,
FIN-02200 Espoo, Finland

Orion Corporation,
Orion Pharma,
Joensuunkatu 7,
FI-24100 Salo, Finland

Distributed in the UK by:
Orion Pharma (UK) Limited,
Oaklea Court,
22 Park Street,
Newbury,
Berkshire,
RG14 1EA

This leaflet was last revised in 06/2018