

Package Leaflet: Information for the user

Frumil® LS 20mg/2.5mg tablets (furosemide/amiloride hydrochloride)

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What Frumil LS Tablets are and what they are used for
- Before you take Frumil LS Tablets
- How to take Frumil LS Tablets
- Possible side effects
- How to store Frumil LS Tablets
- Further information

1. What Frumil LS Tablets are and what they are used for

What Frumil LS Tablets are

The name of your medicine is Frumil LS 20mg/2.5mg Tablets (called Frumil LS Tablets throughout this leaflet). Frumil LS Tablets contain two different medicines called: furosemide and amiloride hydrochloride. Both belong to a group of medicines called diuretics (water tablets).

What Frumil LS Tablets are used for

Frumil LS Tablets can be used to stop the build up of extra water in your body. This extra water can cause swollen ankles, shortness of breath and feeling more tired than usual.

How Frumil LS Tablets work

Frumil LS 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 Frumil LS Tablets

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to furosemide, amiloride hydrochloride or any of the other ingredients of Frumil LS 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 sulphonamides such as sulfadiazine or co-trimoxazole
- You have severe problems with your kidneys
- You have severe liver problems
- Your doctor has told you that you have a low blood volume or are dehydrated
- You are not passing any water (urine)
- You have too much or too little potassium or sodium in your blood (shown in blood tests)
- 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)
- If the person taking the medicine is under 18 years.
Frumil LS Tablets are not suitable for children

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

Take special care with Frumil LS Tablets Check with your doctor or pharmacist before taking your medicine if:

- You have difficulty in passing water (urine)
- You are 65 years of age or older
- You have liver or kidney problems
- You are an elderly patient with dementia and are also taking risperidone
- You have diabetes
- You have low blood pressure or feel dizzy when you stand up
- 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 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 Frumil LS Tablets.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Frumil LS Tablets can affect the way some other medicines work.

Also, some medicines can affect the way Frumil LS 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 Frumil LS Tablets work and increase the chance of you getting side effects:

- Medicines 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 as a general anaesthetic for relaxing your muscles during surgery
- Medicines for diabetes. These may not work as well when you are taking Frumil LS Tablets.
- Theophylline - used for wheezing or difficulty in breathing
- Phenytoin - used for epilepsy. This can lower the effect of Frumil LS Tablets

The following medicines can increase the chance of side effects when taken with Frumil LS 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
- Ciclosporin - used to stop the rejection of organs after a transplant
- Methotrexate - used for cancers of the skin, joint or bowel diseases
- Carbenoxolone - used for ulcers of the food-pipe (gullet)
- Reboxetine - used for depression
- Amphotericin - used for fungal infections if used for a long time
- Corticosteroids - used for inflammation such as prednisolone
- 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
- 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
- Other water tablets (diuretics) such as bendroflumethiazide.
Your doctor may need to change the dose of your medicine

Pregnancy and breast-feeding

Do **not** take Frumil LS 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 Frumil LS 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 breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Frumil LS Tablets

This medicine contains:

- A colour called 'sunset yellow' (E110). This may cause allergic reactions.
- Lactose monohydrate. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine

3. How to take Frumil LS Tablets

Always take Frumil LS Tablets exactly as your doctor has told 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 feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much Frumil LS Tablets to take

The usual dose is one or two tablets first thing in the morning. Your doctor will tell you how many tablets to take.

If you are taking sucralfate (a medicine for stomach ulcers)

Do not take sucralfate at the same time as Frumil LS Tablets. Take your dose at least 2 hours before or after Frumil LS Tablets. This is because it can affect the way your medicine works.

If you take more Frumil LS Tablets than you should

If you think you may have taken more Frumil LS Tablets than you should, or if a child has swallowed any of your tablets, tell your doctor or got to your nearest hospital casualty department straight away. Remember to take with you any medicine that is left so the doctor knows what you have taken. The following effects may happen: dry mouth, feeling thirsty, muscle pain or cramps, feeling sick or being sick (vomiting), weak or uneven heartbeat, feeling dizzy, weak or sleepy.

If you forget to take Frumil LS Tablets

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

If you stop taking Frumil LS Tablets

Keep taking Frumil LS 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, Frumil LS Tablets can cause side effects, although not everybody gets them.

Tell a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment

- If you have an allergic reaction. The signs may include inflammation of the kidney (nephritis), swollen ankles or high blood pressure, skin rashes, change in skin colour, severe blistering of the skin, being more sensitive to the sun than usual, high temperature (fever), and itching
- Severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- Severe stomach or back pain. These could be signs of 'pancreatitis'
- Bruising more easily, getting more infections, feeling weak or tired more than usual. Frumil LS Tablets can affect the number of blood cells, causing serious blood problems
- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can also lead to blood clots or 'gout'
- You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem. In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur. Symptoms include forgetfulness, fits, mood changes and coma.
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome. In a more severe form of the condition called Toxic Epidermal Necrolysis, layers of the skin may peel off to leave large areas of raw exposed skin all over the body.

Tell a doctor as soon as possible if you have any of the following side effects:

- Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- Deafness
- Tingling or feeling numb on the skin
- Small changes in your mood such as feeling agitated or anxious.
- Headaches, feeling dizzy or light-headed when standing up quickly. Also loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

- Feeling sick (nausea) or a general feeling of being unwell, diarrhoea and being sick (vomiting) and constipation
- People with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed
- If you have diabetes you may be less able to control the levels of glucose in your blood
- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.

Blood tests

Frumil LS Tablets can change the levels of liver enzymes or body fats known as cholesterol and triglycerides shown up on blood tests.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.

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

5. How to store Frumil LS Tablets

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not take Frumil LS Tablets after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month
- Do not store above 25°C.
- Store in the original package to protect from light.
- If your doctor decides to stop the treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.
- If your medicine appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- 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 Frumil LS Tablets contain

The active ingredients are furosemide and amiloride hydrochloride.

- Each tablet contains 20mg furosemide and 2.5mg amiloride hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycollate, talc, sunset yellow dye (E110), colloidal anhydrous silica and magnesium stearate.

What Frumil LS Tablets look like and contents of the pack

Frumil LS tablets are orange, circular, bevelled edge marked with the letters 'LS' on one side and plain on the reverse.

Frumil LS Tablets are available in blister packs of 28.

Manufacturer

Manufactured by: Sanofi-Aventis S.p.A,
Strada Statale 17, Km 22, 67019 Scoppito (L'Aquila), Italy.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

PL No: 21828/0624

POM

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Leaflet issue and revision date (Ref): 30.01.15

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Package Leaflet: Information for the user

Donafruise LS 20mg/2.5mg tablets (furosemide/amiloride hydrochloride)

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

In this leaflet:

- What Donafruise LS Tablets are and what they are used for
- Before you take Donafruise LS Tablets
- How to take Donafruise LS Tablets
- Possible side effects
- How to store Donafruise LS Tablets
- Further information

1. What Donafruise LS Tablets are and what they are used for

What Donafruise LS Tablets are

The name of your medicine is Donafruise LS 20mg/2.5mg Tablets (called Donafruise LS Tablets throughout this leaflet). Donafruise LS Tablets contain two different medicines called: furosemide and amiloride hydrochloride. Both belong to a group of medicines called diuretics (water tablets).

What Donafruise LS Tablets are used for

Donafruise LS Tablets can be used to stop the build up of extra water in your body. This extra water can cause swollen ankles, shortness of breath and feeling more tired than usual.

How Donafruise LS Tablets work

Donafruise LS 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 Donafruise LS Tablets

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to furosemide, amiloride hydrochloride or any of the other ingredients of Donafruise LS 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 sulphonamides such as sulfadiazine or co-trimoxazole
- You have severe problems with your kidneys
- You have severe liver problems
- Your doctor has told you that you have a low blood volume or are dehydrated
- You are not passing any water (urine)
- You have too much or too little potassium or sodium in your blood (shown in blood tests)
- 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)
- If the person taking the medicine is under 18 years.
Donafruise LS Tablets are not suitable for children

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

Take special care with Donafruise LS Tablets Check with your doctor or pharmacist before taking your medicine if:

- You have difficulty in passing water (urine)
- You are 65 years of age or older
- You have liver or kidney problems
- You are an elderly patient with dementia and are also taking risperidone
- You have diabetes
- You have low blood pressure or feel dizzy when you stand up
- 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 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 Donafruise LS Tablets.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Donafruise LS Tablets can affect the way some other medicines work.

Also, some medicines can affect the way Donafruise LS 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 Donafruise LS Tablets work and increase the chance of you getting side effects:

- Medicines 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 as a general anaesthetic for relaxing your muscles during surgery
- Medicines for diabetes. These may not work as well when you are taking Donafruise LS Tablets.
- Theophylline - used for wheezing or difficulty in breathing
- Phenytoin - used for epilepsy. This can lower the effect of Donafruise LS Tablets

The following medicines can increase the chance of side effects when taken with Donafruise LS 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
- Ciclosporin - used to stop the rejection of organs after a transplant
- Methotrexate - used for cancers of the skin, joint or bowel diseases
- Carbenoxolone - used for ulcers of the food-pipe (gullet)
- Reboxetine - used for depression
- Amphotericin - used for fungal infections if used for a long time
- Corticosteroids - used for inflammation such as prednisolone
- 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
- 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
- Other water tablets (diuretics) such as bendroflumethiazide. Your doctor may need to change the dose of your medicine

Pregnancy and breast-feeding

Do **not** take Donafruise LS 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 Donafruise LS 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 breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Donafruise LS Tablets

This medicine contains:

- A colour called 'sunset yellow' (E110). This may cause allergic reactions.
- Lactose monohydrate. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine

3. How to take Donafruise LS Tablets

Always take Donafruise LS Tablets exactly as your doctor has told 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 feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much Donafruise LS Tablets to take

The usual dose is one or two tablets first thing in the morning. Your doctor will tell you how many tablets to take.

If you are taking sucralfate (a medicine for stomach ulcers)

Do not take sucralfate at the same time as Donafruise LS Tablets. Take your dose at least 2 hours before or after Donafruise LS Tablets. This is because it can affect the way your medicine works.

If you take more Donafruise LS Tablets than you should

If you think you may have taken more Donafruise LS Tablets than you should, or if a child has swallowed any of your tablets, tell your doctor or got to your nearest hospital casualty department straight away. Remember to take with you any medicine that is left so the doctor knows what you have taken.

The following effects may happen: dry mouth, feeling thirsty, muscle pain or cramps, feeling sick or being sick (vomiting), weak or uneven heartbeat, feeling dizzy, weak or sleepy.

If you forget to take Donafruise LS Tablets

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

If you stop taking Donafruise LS Tablets

Keep taking Donafruise LS 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, Donafruise LS Tablets can cause side effects, although not everybody gets them.

Tell a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment

- If you have an allergic reaction. The signs may include inflammation of the kidney (nephritis), swollen ankles or high blood pressure, skin rashes, change in skin colour, severe blistering of the skin, being more sensitive to the sun than usual, high temperature (fever), and itching
- Severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- Severe stomach or back pain. These could be signs of 'pancreatitis'
- Bruising more easily, getting more infections, feeling weak or tired more than usual. Donafruise LS Tablets can affect the number of blood cells, causing serious blood problems
- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can also lead to blood clots or 'gout'

- You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem. In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur. Symptoms include forgetfulness, fits, mood changes and coma.
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome. In a more severe form of the condition called Toxic Epidermal Necrolysis, layers of the skin may peel off to leave large areas of raw exposed skin all over the body.

Tell a doctor as soon as possible if you have any of the following side effects:

- Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- Deafness
- Tingling or feeling numb on the skin
- Small changes in your mood such as feeling agitated or anxious.
- Headaches, feeling dizzy or light-headed when standing up quickly. Also loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

- Feeling sick (nausea) or a general feeling of being unwell, diarrhoea and being sick (vomiting) and constipation
- People with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed
- If you have diabetes you may be less able to control the levels of glucose in your blood
- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.

Blood tests

Donafuse LS Tablets can change the levels of liver enzymes or body fats known as cholesterol and triglycerides shown up on blood tests.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.

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

5. How to store Donafuse LS Tablets

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not take Donafuse LS Tablets after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month
- Do not store above 25°C.
- Store in the original package to protect from light.
- If your doctor decides to stop the treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.
- If your medicine appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- 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 Donafuse LS Tablets contain

The active ingredients are furosemide and amiloride hydrochloride.

- Each tablet contains 20mg furosemide and 2.5mg amiloride hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycollate, talc, sunset yellow dye (E110), colloidal anhydrous silica and magnesium stearate.

What Donafuse LS Tablets look like and contents of the pack

Donafuse LS tablets are orange, circular, bevelled edge marked with the letters 'LS' on one side and plain on the reverse.

Donafuse LS Tablets are available in blister packs of 28.

Manufacturer

Manufactured by: Sanofi-Aventis S.p.A, Strada Statale 17, Km 22, 67019 Scoppito (L'Aquila), Italy.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

PL No: 21828/0624

POM

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Leaflet issue and revision date (Ref): 30.01.15

Package Leaflet: Information for the user

Co-Amilorfruse LS 20mg/2.5mg tablets (furosemide/amiloride hydrochloride)

Read all of this leaflet carefully before you start taking this medicine

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- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What Co-Amilorfruse LS Tablets are and what they are used for
- Before you take Co-Amilorfruse LS Tablets
- How to take Co-Amilorfruse LS Tablets
- Possible side effects
- How to store Co-Amilorfruse LS Tablets
- Further information

1. What Co-Amilorfruse LS Tablets are and what they are used for

What Co-Amilorfruse LS Tablets are

The name of your medicine is Co-Amilorfruse LS 20mg/2.5mg Tablets (called Co-Amilorfruse LS Tablets throughout this leaflet). Co-Amilorfruse LS Tablets contain two different medicines called: furosemide and amiloride hydrochloride. Both belong to a group of medicines called diuretics (water tablets).

What Co-Amilorfruse LS Tablets are used for

Co-Amilorfruse LS Tablets can be used to stop the build up of extra water in your body. This extra water can cause swollen ankles, shortness of breath and feeling more tired than usual.

How Co-Amilorfruse LS Tablets work

Co-Amilorfruse LS 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 Co-Amilorfruse LS Tablets

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to furosemide, amiloride hydrochloride or any of the other ingredients of Co-Amilorfruse LS 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 sulphonamides such as sulfadiazine or co-trimoxazole
- You have severe problems with your kidneys
- You have severe liver problems
- Your doctor has told you that you have a low blood volume or are dehydrated
- You are not passing any water (urine)
- You have too much or too little potassium or sodium in your blood (shown in blood tests)
- 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)
- If the person taking the medicine is under 18 years.
Co-Amilorfruse LS Tablets are not suitable for children

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

Take special care with Co-Amilorfruse LS Tablets Check with your doctor or pharmacist before taking your medicine if:

- You have difficulty in passing water (urine)
- You are 65 years of age or older
- You have liver or kidney problems
- You are an elderly patient with dementia and are also taking risperidone
- You have diabetes
- You have low blood pressure or feel dizzy when you stand up
- 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 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 Co-Amilorfruse LS Tablets.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Co-Amilorfruse LS Tablets can affect the way some other medicines work.

Also, some medicines can affect the way Co-Amilorfruse LS 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 Co-Amilorfruse LS Tablets work and increase the chance of you getting side effects:

- Medicines 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 as a general anaesthetic for relaxing your muscles during surgery
- Medicines for diabetes. These may not work as well when you are taking Co-Amilorfruse LS Tablets.
- Theophylline - used for wheezing or difficulty in breathing
- Phenytoin - used for epilepsy. This can lower the effect of Co-Amilorfruse LS Tablets

The following medicines can increase the chance of side effects when taken with Co-Amilorfruse LS 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
- Ciclosporin - used to stop the rejection of organs after a transplant
- Methotrexate - used for cancers of the skin, joint or bowel diseases
- Carbenoxolone - used for ulcers of the food-pipe (gullet)
- Reboxetine - used for depression
- Amphotericin - used for fungal infections if used for a long time
- Corticosteroids - used for inflammation such as prednisolone
- 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
- 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
- Other water tablets (diuretics) such as bendroflumethiazide. Your doctor may need to change the dose of your medicine

Pregnancy and breast-feeding

Do **not** take Co-Amilorfruse LS 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 Co-Amilorfruse LS 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 breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Co-Amilorfruse LS Tablets

This medicine contains:

- A colour called 'sunset yellow' (E110). This may cause allergic reactions.
- Lactose monohydrate. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking this medicine

3. How to take Co-Amilorfruse LS Tablets

Always take Co-Amilorfruse LS Tablets exactly as your doctor has told 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 feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much Co-Amilorfruse LS Tablets to take

The usual dose is one or two tablets first thing in the morning. Your doctor will tell you how many tablets to take.

If you are taking sucralfate (a medicine for stomach ulcers)

Do not take sucralfate at the same time as Co-Amilorfruse LS Tablets. Take your dose at least 2 hours before or after Co-Amilorfruse LS Tablets. This is because it can affect the way your medicine works.

If you take more Co-Amilorfruse LS Tablets than you should

If you think you may have taken more Co-Amilorfruse LS Tablets than you should, or if a child has swallowed any of your tablets, tell your doctor or got to your nearest hospital casualty department straight away. Remember to take with you any medicine that is left so the doctor knows what you have taken. The following effects may happen: dry mouth, feeling thirsty, muscle pain or cramps, feeling sick or being sick (vomiting), weak or uneven heartbeat, feeling dizzy, weak or sleepy.

If you forget to take Co-Amilorfruse LS Tablets

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

If you stop taking Co-Amilorfruse LS Tablets

Keep taking Co-Amilorfruse LS 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, Co-Amilorfruse LS Tablets can cause side effects, although not everybody gets them.

Tell a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment

- If you have an allergic reaction. The signs may include inflammation of the kidney (nephritis), swollen ankles or high blood pressure, skin rashes, change in skin colour, severe blistering of the skin, being more sensitive to the sun than usual, high temperature (fever), and itching
- Severe allergic reactions. The signs may include shock such as difficulty in breathing, cold clammy skin, pale skin colour and racing heart beat
- Severe stomach or back pain. These could be signs of 'pancreatitis'
- Bruising more easily, getting more infections, feeling weak or tired more than usual. Co-Amilorfruse LS Tablets can affect the number of blood cells, causing serious blood problems

- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can also lead to blood clots or 'gout'
- You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem. In patients who already have liver problems, a more serious liver problem known as liver encephalopathy may occur. Symptoms include forgetfulness, fits, mood changes and coma.
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome. In a more severe form of the condition called Toxic Epidermal Necrolysis, layers of the skin may peel off to leave large areas of raw exposed skin all over the body.

Tell a doctor as soon as possible if you have any of the following side effects:

- Problems hearing or ringing in the ears (tinnitus). This especially affects people who already have problems with their kidneys
- Deafness
- Tingling or feeling numb on the skin
- Small changes in your mood such as feeling agitated or anxious.
- Headaches, feeling dizzy or light-headed when standing up quickly. Also loss of concentration, slower reactions, feeling sleepy or weak, problems with your sight, dry mouth. This could be due to low blood pressure

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

- Feeling sick (nausea) or a general feeling of being unwell, diarrhoea and being sick (vomiting) and constipation
- People with bladder and prostate problems may notice pain when passing water. This is due to an increase in the amount of water passed
- If you have diabetes you may be less able to control the levels of glucose in your blood
- Passing more water (urine) than you usually do. This normally happens 1 or 2 hours after taking this medicine.

Blood tests

Co-Amilorfruse LS Tablets can change the levels of liver enzymes or body fats known as cholesterol and triglycerides shown up on blood tests.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.

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

5. How to store Co-Amilorfruse LS Tablets

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not take Co-Amilorfruse LS Tablets after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month
- Do not store above 25°C.
- Store in the original package to protect from light.
- If your doctor decides to stop the treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.
- If your medicine appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.
- 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 Co-Amilorfruse LS Tablets contain

The active ingredients are furosemide and amiloride hydrochloride.

- Each tablet contains 20mg furosemide and 2.5mg amiloride hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, sodium starch glycollate, talc, sunset yellow dye (E110), colloidal anhydrous silica and magnesium stearate.

What Co-Amilorfruse LS Tablets look like and contents of the pack

Co-Amilorfruse LS tablets are orange, circular, bevelled edge marked with the letters 'LS' on one side and plain on the reverse

Co-Amilorfruse LS Tablets are available in blister packs of 28.

Manufacturer

Manufactured by: Sanofi-Aventis S.p.A, Strada Statale 17, Km 22, 67019 Scoppito (L'Aquila), Italy.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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