PACKAGE LEAFLET

Package leaflet: Information for the user

Furosemid Medical Valley 20 mg tablets
Furosemid Medical Valley 40 mg tablets
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 <invented name> is and what it is used for

<Invented name> is used to treat:
- **swelling caused by excess fluid in the tissues**, occurring in patients with
  - heart disease
  - liver disease
  - kidney disease
    This also includes a kidney disease with massive protein loss, increased fat levels and swelling through fluid accumulation. If you have this particular kidney disease, treatment of the underlying disorder has priority.
- **swelling in the lung caused by excess fluid**
- **high blood pressure**

<Invented name> is a diuretic, which is a medicine that increases urine output.

2. What you need to know before you take <invented name>

Do not take <invented name> if you
- are allergic to
  - furosemide or any of the other ingredients of this medicine (listed in section 6).
  - medicines similar in chemical structure to furosemide, known as sulfonamides, which are used to treat bacterial infections, diabetes, increased eye pressure or to increase urine output
- have kidney failure with insufficient urine production and not responding to furosemide.
- have been told that you have a low blood volume of fluid in your body or are dehydrated (with or without accompanying low blood pressure).
- have electrolyte deficiency (e.g., lower potassium or sodium levels in your blood as shown in blood test).
- are breast-feeding (see section Pregnancy and breast-feeding).
- have an illness called ‘Addison's Disease’. This can make you feel tired and weak.
- have severe problems with your liver (cirrhosis).

Warnings and precautions
Talk to your doctor or pharmacist before taking <invented name>:
- if you have **low blood pressure or if you are at risk of pronounced fall in blood pressure** (e.g. due to medical conditions like circulatory disorders of the brain vessels or heart disorder).
- if you have **diabetes** (high blood sugar). Regular blood sugar level monitoring is recommended.
- if you have **reduced kidney function**, including patients with liver diseases, known as hepatorenal syndrome. Your doctor may need to adjust your dose of <invented name>.
- if you have **low level of protein in your blood** (hypoproteinaemia). Your doctor will carefully adjust your dose of <invented name>.
- if you have **gout**. Regular uric acid level monitoring is recommended.
- if you are going to give this medicine to a **baby that was born too early**.
- if you are **elderly**.
- if you have **urinary flow disorders** caused for example by an enlarged prostate gland, or reduced urination. Your doctor will carefully monitor your urinary output.
- if you have a **risk of reduced mineral levels, abnormal changes in the amount of acid and base** in the body which can occur if you have lost a lot of water through being sick, having diarrhoea or intense sweating, have other diseases (liver or heart disorder) or use other medicines (See subsection “Other medicines and <invented name>”). In general, your doctor will monitor your blood levels of minerals, uric acid, glucose and creatinine regularly, particularly so in high-risk patients and in long-term therapy. Mineral and acid base disturbances must be corrected. Your doctor may temporarily stop <invented name> treatment.
- if you have **inflammatory disease** which causes joint pain, skin rashes and fever (systemic lupus erythematosus). There is a possibility of worsening or triggering of disease.
- if you are taking **other medicines**, see subsection “Other medicines and <invented name>”.

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

Other medicines and <invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines can affect or be affected by <invented name>:
- **medicines to treat inflammation and pain**, such as acetylsalicylic acid and indomethacin
- **medicines to encourage the heart’s pumping strength**, such as digitoxin, digoxin or methyldigoxin
- medicines that cause a certain heartbeat abnormality known as QT prolongation, such as
  - **terfenadine**, a medicine to treat allergies
  - certain **medicines to treat irregular heartbeat**
- **medicines to treat infections**, such as
  - medicines with active substance names beginning with "cef"
  - kanamycin, gentamycin, tobramycin
  - polymyxin
- other **medicines which cause ear damages**
- **medicines to treat high blood pressure**, such as
  - aliskiren
  - other medicines that increase urine output
  - medicines with active substance names ending in “pril”. Your doctor may need to reduce the dose or temporarily stop the treatment with <invented name>.
  - medicines with active substance names ending in “sartan”
  - other medicines that reduce blood pressure
- **lithium**, a medicine to treat depression and mental disorders
  Your doctor will carefully check your lithium blood level.
- **risperidone**, a medicine to treat mental disorders

Your doctor will very carefully assess the risks and benefits of simultaneous treatment with <invented name>. This applies especially in elderly patients with dementia.
- **chloral hydrate**, a medicine to treat sleep disorders
  Avoid taking <invented name> while using chloral hydrate.
- **sucralfat**, a medicine to treat stomach and bowel ulcers
  Do not take <invented name> and sucralfat within 2 hours of each other.
- **medicines to treat diabetes**
- medicines used to increase blood pressure and slow heart rate in certain shock situations, such as **epinephrine, norepinephrine**
- **theophylline**, a medicine to treat asthma and other breathing diseases
- some **muscle-relaxant medicines** with active substances ending in “curonium” or “curium”
- **cisplatin**, a medicine to treat cancer
  Your doctor will prescribe you the lowest possible <invented name> dose and a positive fluid balance is recommended.
- **phenytoin**, a medicine to treat epilepsy and certain pain conditions
- **carbamazepine**, a medicine to treat epilepsy, certain pain conditions and euphoric/depressive stages
- **aminoglutethimide**, a medicine to treat breast cancer and a disease characterised with rounded, moon-shaped face known as Cushing's syndrome
- **corticosteroids**, medicines to treat inflammation or prevent organ transplant rejection, such as cortisone
- **carbenoxolone**, a medicine to treat gullet ulceration and inflammation
- **medicines to treat constipation**
- **probenecid**, a medicine to treat gout
- **methotrexate**, a medicine to treat severe joint inflammation, cancer and psoriasis
- **ciclosporin**, a medicine to suppress transplant rejection, treat severe skin diseases and severe eye or joint inflammation
- **contrast media**, medicines used in X-ray procedures to image organs or vessels

<Invented name> with food
Avoid large amounts of liquorice products when taking <invented name>.

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

Pregnancy
Only take <invented name> during pregnancy if your doctor indicates that it is absolutely necessary. If <invented name> is taken during pregnancy, your doctor will carefully monitor:
- your mineral levels
- the percentage of blood cells in the blood volume
- the growth of the unborn child

Breast-feeding
Do not take <invented name> if you are breast-feeding.

Driving and using machines
This medicine may make you feel dizzy and unwell. Do not drive or operate machinery if this happens.

<Invented name> contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

<Invented name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 20 mg /40 mg tablet, that is to say it is essentially ‘sodium-free’.

3. How to take <invented name>

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

Take the tablets at least half an hour before a meal, with one glass of water.
<invented name> 40 mg tablets can be divided into two equal doses.
The number of tablets you need will depend on your condition.

Adults
The recommended initial adult dose is 20-40 mg daily. The dose should be adjusted until the lowest effective dose is achieved. In some patients, daily doses of 80 mg or higher may be needed.

Use in children and adolescents
In children, the dose should be reduced according to bodyweight and calculated by the doctor. The recommended dose is from 1 to 3 milligrams per 1 kilogram of bodyweight.

Patients with impaired liver function
Your doctor may adjust your dose if your liver function is moderately or severely impaired. See also section 2, “Do not take <invented name>”.

Patients with impaired kidney function
Your doctor may need to adjust your dose of <invented name>.

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 take more <invented name> than you should
If you or your child accidentally take too many tablets, tell your doctor immediately or contact your nearest hospital, even if there are no signs of discomfort. Take the medicine in its original packaging with you for the doctor to identify your medication easily.

Taking too much of <invented name> may make you:
- feel confused, unable to focus, show a lack emotion or interest in anything
- dizzy, lightheaded, fainting
- experience uneven heartbeat, muscle weakness or cramps and clots (signs include pain and swelling at the part of body that is affected)
- may have problems with your kidneys or blood.

If you forget to take <invented name>
Do not take a double dose to make up for a forgotten dose. Take the forgotten dose as soon as possible on the same day or take the next dose as usual the next day.

If you stop taking <invented name>
Do not stop taking <invented name> without your doctor’s permission, as this can seriously harm you and reduce the therapy effect.

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.

Stop taking this medicine and tell your doctor or go to your nearest emergency department immediately if you suffer from any of the following:

- Severe allergic reaction. The signs may include hives, swelling of the face, lips, tongue or throat, difficulty in breathing, cold clammy skin, pale skin colour and racing heartbeat (rare: may affect up to 1 in 1,000 people).
- Severe stomach or back pain. These could be signs of inflammation of the pancreas (very rare: may affect up to 1 in 10,000 people).
- Bruising more easily (uncommon: may affect up to 1 in 100 people), getting more infections, sudden high fever, severe sore throat and ulcers in the mouth (rare: may affect up to 1 in 1,000 people), feeling weak or tired more than usual, pale skin, breathlessness, dark urine (very rare: may affect up to 1 in 10,000 people). These could be signs of a low number of different types of blood cells.
- Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, upsets stomach or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals (very common: may affect more than 1 in 10 people).
- Yellowing of the skin or eyes and dark-brown coloured urine. These could be signs of a liver problem (very rare: may affect up to 1 in 10,000 people). In patients who already have liver problems, a more serious liver problem that affects brain function (known as liver encephalopathy) may occur. Symptoms include forgetfulness, fits, mood changes and coma (common: may affect up to 1 in 10 people).
- A widespread skin rash, blistering or peeling of the skin around the lips, eyes, mouth, nose, genitals or other parts of the body, flu-like symptoms and fever. These could be signs of a serious skin reaction (such as Stevens-Johnson syndrome, Toxic Epidermal Necrolysis, drug rash with eosinophilia and systemic symptoms (DRESS) or acute generalised exanthematous pustulosis (AGEP)) (frequency cannot be estimated from the available data).
- Unexplained muscle pain, tenderness or weakness. This might be a sign of a potentially severe muscle degradation (frequency cannot be estimated from the available data).
- Not going to the toilet (low urine output), nausea, tiredness, pain in your sides, swelling of your legs or blood in your urine. These could be signs of a kidney problem (frequency cannot be estimated from the available data).

Other side effects can occur with the following frequencies:

Very common: may affect more than 1 in 10 people
- reduced blood volume
- increased blood fat concentration known as triglyceride
- lower than normal blood pressure
- circulation problems, especially when standing up
  These circulation problems may include circulatory collapse
- increased blood concentrations of creatinine

Common: may affect up to 1 in 10 people
- increased concentration of blood cells as a result of fluid loss
- reduced potassium, sodium and chloride levels in blood
- increased blood concentrations of uric acid, gout
- increased blood fat level known as cholesterol
- increased amount of urine

Uncommon: may affect up to 1 in 100 people
- allergic skin and mucous membrane reactions
- increased blood sugar levels
- hearing disorders, usually reversible, especially in patients with reduced kidney function or low protein levels in the blood
- deafness (sometimes irreversible)
- nausea

- itching
- nettle-rash, skin rash
- severe inflammation of skin and inner lining, with signs such as blisters and fever (bullous erythema multiforme, bullous pemphigoid, dermatitis exfoliative)
- red or purple spots on the skin
- increased light sensitivity

Rare: may affect up to 1 in 1,000 people
- increased number of certain white blood cells known as eosinophylic granulocytes
- sensation disorder such as tingling, prickling, burning or numbness
- ringing or buzzing in the ears
- kidney inflammation, affecting the fluid that surround the kidney tubules
- inflammation of blood vessels
- vomiting, diarrhoea
- fever

Very rare: may affect up to 1 in 10,000 people
- increase of certain liver enzyme levels, known as transaminases

Not known: frequency cannot be estimated from the available data
- worsening or triggering of an inflammatory disease which causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- excessive alkaline level in the blood, salt loss and low blood pressure due to a kidney disease (Pseudo-Bartter syndrome), related to misuse and/or long-term use of this medicine
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension) headache
- increased risk of the blood vessel connecting the lung artery and aortic arch not closing, if furosemide is given to premature infants during the first weeks of life
- reduced calcium or magnesium levels in the blood
- blood clot which may block a blood vessel
- increased sodium or chloride levels in the urine
- increased blood concentration of urea
- urinary obstruction up to acute urinary retention
- deposition of calcium salts in kidney vessels and tissue and/or urinary stones in the kidney of premature infants

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the blister, carton or bottle after ‘EXP’. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage condition.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater. 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 <invented name> contains
<invented name> 20 mg tablets:
- The active substance is furosemide. 1 tablet contains 20 mg of furosemide.

<invented name> 40 mg tablets:
- The active substance is furosemide. 1 tablet contains 40 mg of furosemide.

- The other ingredients are: lactose monohydrate (E1410), maize starch, pregelatinised starch, sodium starch glycolate (Type A), magnesium stearate (E470b), purified water.

What <invented name> looks like and contents of the pack
<invented name> 20 mg tablets:
White to off white round tablets, approximately 6 mm in diameter, marked with “F 20” on one side and plainC on the other side.

<Invented name> 40 mg tablets:
White or off white circular tablets, approximately 8 mm in diameter, marked with “F 40“ on one side (F and 40 are separated by break line) and plain on the other side.
The tablets can be divided into equal doses.

Blister pack: <Invented name> is supplied in opaque PVDC /PVC/Aluminium blister of 10 tablets with pack size: 30, 90, 100 tablets.

Bottle pack:
<Invented name> 20 mg is also supplied in a HDPE bottle with a polypropylene screw cap in the pack sizes: 105, 110, 500 tablets.

<Invented name> 40 mg is also supplied in a HDPE bottle with a polypropylene screw cap in the pack sizes: 105, 110, 270, 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Denmark	Furosemid “Medical Valley”
Netherlands	Furosemide Xiromed 20 mg, tabletten
	Furosemide Xiromed 40 mg, tabletten
Sweden	Furosemid Medical Valley

This leaflet was last revised in 2024-07-08.

<Other sources of information>
<Detailed information on this medicine is available on the website of {name of Member State Agency (link)}>**.**