Package leaflet: Information for the patient

Furosemid Hexal 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 Furosemid Hexal is and what it is used for

Furosemid Hexal 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**

Furosemid Hexal is a diuretic, which is a medicine that increases the urine output.

2. What you need to know before you take Furosemid Hexal

Do not take Furosemid Hexal if you
- are **allergic** to:
  - furosemide
  - medicines similar in chemical structure to furosemide, known as sulphonamides and used to treat bacterial infections, diabetes, increased eye pressure or to increase the urine output
  - or any of the other ingredients of this medicine (listed in section 6)
- have **kidney failure** with insufficient urine production and not responding to furosemide
- have **a severe liver disorder** that affects brain function
- have **severely reduced potassium** or **sodium level** in the blood
- have **reduced blood volume** or **dehydration**
  If any of these two conditions occur during treatment your doctor may stop Furosemid Hexal therapy and treat these disturbances.
- are **breast-feeding**

Warnings and precautions
Talk to your doctor or pharmacist before taking Furosemid Hexal if any of the following apply to you:
- reduced blood pressure
- diabetes
  Undetected diabetes may become apparent. Regular blood sugar level monitoring is recommended.
- gout
  Regular uric acid level monitoring is recommended.
- urinary flow disorders caused for example by an enlarged prostate gland, or reduced urination
  Your doctor will carefully monitor your urinary output.
- reduced protein levels in the blood
  Your doctor will carefully adjust the Furosemid Hexal dose.
- reduced kidney function, including patients with liver diseases, known as hepatorenal syndrome
  Your doctor may need to adjust the Furosemid Hexal dose.
- at risk of pronounced fall in blood pressure (if you have for example circulatory disorders of the brain vessels or heart disorder)
- premature infants
  The doctor will monitor the kidney function. This is due to the possible formation of kidney stones. Special medical care is required during the first weeks of life in premature infants with certain breathing difficulties.
- 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 a drop in blood pressure
- 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 “Other medicines and Furosemid Hexal).
  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 Furosemid Hexal treatment.
- long-term treatment with Furosemid Hexal
  Potassium rich diet is recommended, such as potatoes, bananas, tomatoes, spinach and dry fruits. Sometimes your doctor may recommend additionally taking potassium-containing medicines or replace Furosemid Hexal with a suitable alternative.
- inflammatory disease which causes joint pain, skin rashes and fever (systemic lupus erythematosus)
  There is a possibility of worsening or triggering of disease.
- taking other medicines
  See section 2, “Other medicines and Furosemid Hexal”.

Other medicines and Furosemid Hexal
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 Furosemid Hexal:
- **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
  - 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 Furosemide Hexal.

  - medicines with active substance names ending in “sartan”
  - other medicines that reduce blood pressure e.g. aliskiren
- **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
  The doctor will very carefully assess the risks and benefits of simultaneous treatment with Furosemid Hexal. This applies especially in elderly patients with dementia.
- **chloral hydrate**, a medicine to treat sleep disorders
  Avoid using Furosemid Hexal while using chloral hydrate.
- **sucralfat**, a medicine to treat stomach and bowel ulcers
  Do not take Furosemid Hexal 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 Furosemid Hexal 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

Furosemid Hexal with food
Avoid large amounts of liquorice products when taking Furosemid Hexal.

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 Furosemid Hexal during pregnancy **if your doctor indicates that it is absolutely necessary**.
  If Furosemid Hexal is used during pregnancy, your doctor will carefully monitor:
  - your mineral levels
  - the percentage of blood cells on the blood volume
  - the growth of the unborn child

- **Breast-feeding**
  Do not take Furosemid Hexal if you are breast-feeding.

Driving and using machines
Furosemid Hexal may cause side effects which might impair the ability to drive and use machines, especially at the beginning of therapy, and on increasing the dose. If your attention is decreased, do not drive or operate machines.

Furosemid Hexal 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.

Furosemid Hexal contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Furosemid Hexal

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.
The tablet can be divided into equal doses.

The doctor will adjust your dose individually until an effective dose is achieved.

The recommended dose for adults and elderly is:

Swelling caused by excess fluid in the tissues

- **starting dose:**
  - ½ to 1 tablet in patients with heart or liver disease
  - 1 tablet in patients with kidney disease

  If the therapy response is unsatisfactory, the doctor may advise you to take up to 2 tablets after 6 hours. An additional dose of 4 tablets can be taken after a further 6 hours, if the response remains unsatisfactory.
  A higher dose may be required in patients with reduced kidney function.

- **maintenance dose:** 1 to 2 tablets daily

High blood pressure

- **usual dose**: 1 tablet once daily
  In severe cases, your doctor may increase the dose to 1 ½ tablets daily.
  Your doctor will prescribe additional medicines to lower blood pressure if the therapy response is insufficient.

Use in children under 18 years

- **starting dose**: calculated by the doctor based on the child's bodyweight
  After no less than 6 to 8 hours, the doctor may increase the dose if the therapy response of the previous dose is unsatisfactory.
- **maximum dose:** 1 tablet daily

Reduced liver function
Your doctor may adjust the dose if you have moderate or severely reduced liver function. See also section 2, "Do not take Furosemid Hexal", third bullet point.

Reduced kidney function
Your doctor may adjust the dose.

Duration of use
To be decided by your attending doctor.

If you take more Furosemid Hexal than you should
Contact your doctor or pharmacist immediately who will treat you appropriately.

If you forget to take Furosemid Hexal
Take the forgotten dose as soon as possible at the same day or take the next dose normally the next day. Do not take a double dose to make up for a forgotten dose.

If you stop taking Furosemid Hexal
Do not stop Furosemid Hexal use 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.

Contact a doctor or go to your nearest emergency department immediately if you get any of the following serious side effects:

- 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, stomach upsets 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), lichenoid reactions) (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
- 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
- allergic skin and mucous membrane reactions
- 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
- sensation disorder such as tingling, prickling, burning or numbness
- inflammation of blood vessels
- vomiting, diarrhoea
- ringing or buzzing in the ears
- kidney inflammation, affecting the fluid that surround the kidney tubules
- fever
- increased number of certain white blood cells known as eosinophylic granulocytes

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
- reduced calcium or magnesium levels in the blood
- 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
- blood clot which may block a blood vessel
- dizziness, fainting and loss of consciousness (caused by symptomatic hypotension), headache
- 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
- increased risk of the blood vessel connecting the lung artery and aortic arch not closing, if this medicine is given to premature infants during the first weeks of life
- worsening or triggering of an inflammatory disease which causes joint pain, skin rashes and fever (systemic lupus erythematosus).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Furosemid Hexal

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, carton and bottle after "EXP". The expiry date refers to the last day of that month.

[Blister]
Keep the blister in the outer carton in order to protect from light.

[Bottle]
This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Furosemid Hexal contains

The active substance is furosemide. Each tablet contains 40 mg of furosemide.

- The other ingredients are microcrystalline cellulose, lactose monohydrate, magnesium stearate, maize starch, sodium starch glycollate.

What Furosemid Hexal looks like and contents of the pack

Furosemid Hexal tablets are round, white, lightly curved with a one-sided score notch.

The tablets are packed in polypropylen/aluminium blisters and inserted in a carton, or packed in a HDPE bottle.

Blister: 10, 12, 14, 20, 28, 30, 50, 56, 60, 84, 100 and 250 tablets
Bottle: 100, 250 and 500 tablets

Not all pack sizes or pack types may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

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