

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

FUROSEMIDE INOVAMED

Tablets

Active ingredient:
Each tablet contains:

Furosemide 40 mg

For information on inactive and allergenic ingredients in the preparation, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic activity

Diuretic for the treatment of pulmonary edema, edema associated with congestive heart failure, cirrhosis of the liver, renal disease and for the treatment of hypertension.

Therapeutic group: Diuretics.

These medicines are administered for treatment of edema, a condition where there is too much water in your body. This condition can occur due to a problem with the heart, lungs, kidneys, liver, blood vessels or high blood pressure. Furosemide Inovamed helps the kidneys to get rid of the extra water that is not needed in the body.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to other sulfonamides, or to any of the additional ingredients contained in the medicine (see section 6 – "Further information").
- You suffer from severe kidney damage which prevents them from functioning properly and producing urine.
- You have very low blood levels of potassium, sodium or other electrolytes or low blood volume (the doctor will be able to advise you).
- You are dehydrated.
- You have low blood pressure.
- You take potassium supplements or potassium-sparing diuretics for treatment of high blood pressure (e.g., amiloride or spironolactone).
- You have altered levels of consciousness and coma due to **liver cirrhosis** (tiredness, weakness, water retention, nausea or vomiting, weight loss or reduced appetite, yellowing of the skin or eyes, itch) or due to **liver encephalopathy** (confusion, altered levels of consciousness and coma as a result of liver failure).
- You have Addison's disease (low levels of secreted corticosteroid hormones).
- You have digitalis poisoning (nausea or vomiting, high levels of potassium in the blood, slow, fast or irregular heart rate).
- You are breastfeeding.

Special warnings regarding use of the medicine

Before treatment with Furosemide Inovamed, tell the doctor if:

- You suffer from low blood volume (hypovolaemia) or are at risk of developing low blood pressure.
- You suffer from low levels of proteins in the blood (hypoproteinaemia) as a result of kidney dysfunction.
- You have liver congestion (slow blood flow through the blood vessels) or other liver problems.
- You have kidney problems.
- You may have diabetes. If you are taking insulin, the doctor may need to adjust your insulin dosage.
- You are elderly. If you are taking other medicines which may cause a decrease in blood pressure and if you have other medical conditions that are risk factors for a decrease in blood pressure.
- You suffer from problems with the prostate gland or difficulty passing urine.
- You suffer from gout.
- You have abnormal blood problems.
- You are about to undergo blood or urine tests.

Tests and follow-up

The doctor may monitor your condition and refer you for blood tests while you are taking this medicine.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Medicines to lower blood pressure (such as ACE inhibitors, renin inhibitors, alpha blockers, calcium channel blockers, diuretics, phenothiazines)
 - Medicines for treatment of mental illness (such as pimozide, amisulpride, sertindole)
 - Medicines for treatment of arrhythmias (such as sotalol, amiodarone, flecainide)
 - Digoxin (for the heart)
 - Moxisylyte for treatment of Raynaud's syndrome
 - Nitrates (for treatment of angina pectoris)
 - Lithium (for treatment of depression or mania)
 - Sucralfate for treatment of stomach ulcers
 - Colestyramine or colestipol for treatment of high cholesterol
 - Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or naproxen
 - Aspirin (for pain)
 - Antibiotics for treatment of infections that affect the kidneys or ears (such as cefaclor, colistin, gentamicin, vancomycin)
 - Amphoterin (for treatment of fungal infections)
 - Chloral hydrate (for treatment of insomnia)
 - Antidepressants (such as monoamine oxidase inhibitors – MAOIs)
 - Medicines for diabetes, such as insulin or tablets
 - Antiepileptics, such as phenytoin or carbamazepine
 - Corticosteroids or antihistamines (for treatment of allergic reactions)
 - Medicines for treatment of attention deficit disorders (ADHD)
 - Medicines for treatment of cancer, such as aldesleukin
 - Levodopa (for treatment of Parkinson's disease)
 - Oral contraceptives
 - Alprostadil for treatment of erectile dysfunction
 - Certain medicines for treatment of asthma, such as theophylline or salbutamol
 - Probenecid for prevention of gout
 - Laxatives taken over a long period of time
 - Medicines or food products containing licorice
- If you are about to undergo a procedure where curariform muscle relaxants (such as vecuronium) or anesthetics will be used, inform the anesthesiologist, dentist or doctor.

Use of the medicine and food

The medicine can be taken with food.

Use of the medicine and alcohol consumption

Avoid drinking alcohol when taking Furosemide Inovamed since it may cause a further decrease in your blood pressure.

Pregnancy, breastfeeding and fertility

If you are pregnant, plan to become pregnant or are breastfeeding, consult the doctor before you take Furosemide Inovamed.

Driving and operating machinery

Do not drive or operate machinery if you feel less alert after taking Furosemide Inovamed.

Important information about some of the ingredients of the medicine

Furosemide Inovamed contains lactose monohydrate, which is a type of sugar. If you have been told by the doctor that you have an intolerance to lactose, or if you cannot digest certain sugars, consult the doctor before taking this medicine. This medicine contains less than 1 mmol (23 mg) sodium per tablet and is therefore considered "sodium-free". Also see section 6 – "Further information"

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Dosage

The dosage and treatment regimen will be determined by the doctor only.

The doctor will adjust the dosage for each patient in accordance with the patient's condition and response.

Do not exceed the recommended dose.

Method of use

There is no information regarding crushing/chewing of the tablet. The tablet can be halved at the break line.

Swallow the tablets with a small amount of water.

The medicine can be taken with food.

If you accidentally take a higher dosage

If you took an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. The symptoms of overdose include dehydration and changes in the levels of certain substances in the blood.

If you forget to take the medicine

If you forgot to take this medicine at the scheduled time, take the next dose as soon as you remember and then take the next dose at the usual time. Do not take a double dose to compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Furosemide Inovamed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer immediately to a doctor or proceed to a hospital if you have one of the following side effects:

- Severe allergic reaction which may include a skin rash, itching, dermatitis, peeling skin, sensitivity to sunlight or sun lamps or fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.
- Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever could be a condition called Stevens-Johnson syndrome.
- Inflammation of blood vessels (vasculitis, which may cause rash, fever and joint or muscle pains) or kidney inflammation (which may change the number of times you pass urine or you may see blood in the urine. You may have fever, feel drowsy, or notice swelling, for example, of the ankle).
- Blood clot (causing pain, swelling or tenderness in the legs).

Additional side effects

Report to the doctor or pharmacist if you notice one of the following side effects:

Very common side effects – effects that occur in more than one user in ten:

- Dehydration, altered balance of fluids and substances in the body (such as sodium, potassium, chlorine, calcium and magnesium) causing dry mouth, weakness, tiredness or drowsiness, restlessness, fits, muscle pain, weakness or cramps, low blood pressure causing reduced concentration and slowed reactions, difficulty urinating, fast or irregular heart rate, nausea and vomiting

Common side effects – effects that occur in 1-10 in 100 users:

- Low blood volume (hypovolaemia)
- Increased blood creatinine and urea values (seen in blood tests)

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- Anemia causing tiredness, breathlessness, unusual bleeding or bruising
- Changes in the body seen in tests, such as levels of cholesterol, glucose, uric acid
- Gout
- Changes in vision including blurred or yellow vision
- Dizziness, sensations of pressure in the head, headache, drowsiness, weakness, changes in vision, dry mouth, dizziness when standing up
- Irregular heart rate
- Muscle cramps or weakness
- Changes in the amount of urine or need to urinate
- Tiredness
- Dry mouth, thirst, nausea or vomiting, changes in bowel movements including diarrhea and constipation
- Deafness (sometimes irreversible)

Rare side effects – effects that occur in 1-10 in 10,000 users:

- Changes in blood cells, such as amount of white blood cells, reduction in the number of platelets causing a rash, fever, sweating, tiredness, and weight loss. The doctor will perform routine blood tests to ensure that no changes have occurred
- Psychiatric disorder (that cannot be classified otherwise) causing delusions, hallucinations, disorganized speech
- Feeling 'pins and needles' or tingling sensation
- Confusion, headache, tiredness, generally unwell feeling, fever
- Ringing in the ears, loss of hearing which is usually reversible
- Symptoms of shock, such as changes in heart rate, breathlessness, cool and clammy skin
- Inflammation of the pancreas causing pain in the abdomen or back and nausea
- Changes in the liver causing yellowing of the skin or whites of the eyes
- Skin rashes

Very rare side effects – effects that occur in less than one in 10,000 users:

- Involuntary movements of the muscle
- Inflammation or failure of the kidney which may cause back pain or changes in the amount of urine or need to urinate

Side effects of unknown frequency (effects whose frequency has not been established yet):

- Worsening of the condition when there were already balances of fluids or substances in the body
- Acute generalized exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- Dizziness, fainting and loss of consciousness (caused by symptomatic hypotension)
- Decreased levels of potassium in the body

Additional side effects in children:

- Increased risk or persistence of patent ductus arteriosus in premature infants
- Kidney stones in infants

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store the medicine in a cool and dry place, at a temperature below 25°C.**
- Do not discard medicines in the wastewater or waste bin. Consult a pharmacist as to how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Lactose monohydrate, maize starch, sodium starch glycolate (type A), magnesium stearate.

What the medicine looks like and the contents of the package:

White to off-white, uncoated, circular, flat beveled-edge tablets debossed with "F" and "40" separated by a break line on one side and plain on other side.

Package type: The medicine is provided in a carton package that contains trays/blisters with a total of 30 tablets.

License holder and importer: Inovamed Pharma Ltd., P.O.B. 2349, Bnei Brak.

Manufacturer: Aurobindo Pharma Ltd., Hyderabad, Telangana, India.

The leaflet was revised in August 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 174-14-36620