

**Fusid Tablets**  
**Tablets**

**Composition**

Each tablet contains:  
Furosemide 40 mg

**For information about inactive ingredients and allergens see section 2 – “Important information about some of this medicine's ingredients” and section 6 – “Additional information”.**

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

**1. What is this 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 problems with the heart, lungs, kidneys, liver, blood vessels or high blood pressure. Fusid Tablets helps the kidneys to get rid of the extra water that is not needed in the body.

**2. Before using this medicine**

**Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient or other sulfonamides or to any of the other ingredients in this medicine (see section 6 – “Additional information”).
- You have severe kidney damage which prevents the kidneys from functioning properly and producing urine.
- You have very low blood levels of potassium, sodium or other electrolytes or low blood volume (your 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 about using this medicine**

**Before treatment with Fusid Tablets, tell your doctor if:**

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

**Tests and follow up**

Your 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 nonprescription medications and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- Medicines for blood pressure lowering (such as medicines from the ACE inhibitor group, 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)
- Amphotericin (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 may be used, inform your anesthetist, dentist or doctor.

**Using this medicine and food**

The medicine can be taken with food.

**Using this medicine and alcohol consumption**

You should avoid drinking alcohol while taking Fusid Tablets as this may cause further lowering of your blood pressure.

**Pregnancy and breastfeeding**

Consult your doctor before you take Fusid Tablets if you are pregnant, planning to become pregnant, or are breastfeeding.

**Driving and using machines**

Do not drive or operate machines if you feel less alert after taking Fusid Tablets.

**Important information about some of this medicine's ingredients**  
Fusid Tablets contain lactose (milk sugar). If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine. See also section 6 – “Additional information”.

**3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

**Dosage**

Only your doctor will determine your dose and how you should take this medicine.

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

**Do not exceed the recommended dose.**

**Mode of administration**

There is no information regarding crushing/chewing the tablet. The tablet can be split at the score line.  
Swallow the tablets with some water.  
The medicine can be taken with food.

**If you have accidentally taken a higher dose**

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Symptoms of an overdose include dehydration and changes in the levels of certain substances in the blood.

**If you forget to take the medicine**

If you forget 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 a forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

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

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

**4. Side effects**

Like with all medicines, using Fusid Tablets may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**If you have any of the following side effects, contact your doctor or go to a hospital immediately:**

- 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**

**Tell your doctor or pharmacist if you notice any of the following side effects:**

**Very common side effects (occur in more than one in 10 users):**

- Dehydration, altered balance of fluid 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 (occur in up to one in 10 users):**

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

**Uncommon side effects (occur in up to one in 100 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 (occur in up to one in 1,000 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. Your doctor will perform regular blood tests to ensure that no changes have occurred.
- Psychiatric disorder (not otherwise classified) causing delusions, hallucinations, disorganized speech
- Feeling 'pins and needles' or tingling sensation
- Confusion, headache, tiredness, generally feeling unwell, 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 (occur in up to 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 (the frequency of these effects has not been established yet):**

- Worsening of condition where 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 you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Store the medicine in a cool and dry place, below 25°C.**
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to destroy medicines you no longer use. These measures will help protect the environment.

**6. Additional information**

**In addition to the active ingredient, this medicine also contains:**  
Lactose, microcrystalline cellulose, starch, crospovidone, povidone, colloidal silicon dioxide, magnesium stearate, propylparaben, butylparaben.

Each tablet contains 36 mg lactose.

**What the medicine looks like and contents of the pack:**  
White, round, flat tablet, embossed with “TEVA” on one side and bisected on the other side of the tablet.

Pack sizes: 25 tablets, 30 tablets, 50 tablets and 1000 tablets  
Not all pack sizes may be marketed.

**Registration holder's name and address:**

Teva Pharmaceutical Industries Ltd.,  
P.O.Box 3190, Petach-Tikva 49131

**The leaflet was revised in December 2020 in accordance with Ministry of Health guidelines**

**Registration number of the medicine in the National Drug Registry of the Ministry of Health: 020.20.20472**