

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

The medicine is dispensed with a doctor's prescription only

Pamid Tablets 2.5 mg

Each tablet contains: Indapamide 2.5 mg.

For inactive ingredients and allergens in the preparation, see the section "Important information about some ingredients of the medicine" and section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children and adolescents under the age of 18.

1. What is the medicine intended for?

A diuretic for treatment of hypertension and edema.

Therapeutic class: The active ingredient belongs to the sulfonamide diuretics group.

2. Before using the medicine

❗ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, to other sulfonamides or to any of the additional ingredients the medicine contains (see section 6).
- You are suffering or have suffered in the past from severe kidney failure and/or liver problems.
- You have a severe liver disease or you are suffering from hepatic encephalopathy (a liver problem that affects the brain and nervous system).
- You have low levels of potassium in the blood.

❗ Special warnings regarding the use of the medicine: Before treatment with Pamid, inform the doctor if:

- You have or have had a liver and/or kidney problem.
- You have or have had a heart rhythm problem.
- You have diabetes.
- You have gout (severe swelling and pain in the joints).
- You have or have had a thyroid or parathyroid disease (which causes too high/low calcium blood levels).
- You have been told by the doctor that you have low levels of potassium in the blood (hypokalemia).
- You have reactions associated with sensitivity to light.
- You have been told by the doctor that you have low levels of sodium in the blood (hyponatremia).
- Your vision is deteriorating or you have eye pain. These may be symptoms of fluid accumulation in the eye's vascular layer (choroidal effusion) or of increased intraocular pressure, which may occur within hours to a week from taking Pamid. Without treatment, this may cause permanent vision loss. Your risk of developing

this is higher if you have previously had allergy to penicillin or sulfonamide.

❗ Tests and follow-up:

Pamid may lead to a decrease in potassium levels. The doctor may monitor your potassium levels in blood tests. Calcium blood levels may need to be monitored in patients with an overactive parathyroid gland.

Glucose levels, which may be affected by this medicine, may need to be monitored.

During treatment with this medicine, you should undergo periodic blood tests and blood pressure tests. Athletes should be aware of the fact that this medicine contains an active ingredient that may lead to a positive result in drug tests.

❗ Drug-drug interactions:

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

- **Lithium.** Pamid and Lithium should not be combined due to the risk of blood Lithium levels rising
- Carbenoxolone (for treatment of ulcers)
- Diuretics, such as bumetanide, furosemide, thiazides and xipamide
- Potassium-sparing diuretics, such as amiloride, spironolactone, triamterene
- Quinidine or cardioglycosides (for treatment of arrhythmias), such as digoxin, disopyramide, amiodarone, sotalol, ibutilide, dofetilide and digitalis
- Lidocaine, flecainide and mexiletine (for treatment of arrhythmias)
- Intravenous erythromycin antibiotic
- Pentamidine (for treatment of certain types of pneumonia and protozoal infections)
- Prazosin (for treatment of hypertension)
- Medicines for treatment of epilepsy such as oxcarbazepine
- Antipsychotics, such as pimozone and sertindole (for treatment of mental disorders)
- Baclofen, which is a muscle relaxant (for treatment of muscle rigidity that occurs in diseases such as multiple sclerosis)
- Allopurinol (for treatment of gout)
- ACE inhibitors (for treatment of hypertension), such as captopril
- Non-steroidal anti-inflammatory drugs, such as aspirin or ibuprofen (for treatment of arthritis)
- Amphotericin B (for treatment of fungal infections)
- Tetracosactide (to evaluate adrenal function for treatment of Crohn's disease)
- Stimulant laxatives (for treatment of constipation)
- Metformin (for treatment of diabetes)
- Antidepressants and neuroleptics (for treatment of mental disorders)

- Immunosuppressants such as cyclosporine, tacrolimus (used to prevent organ rejection after transplantation, or for treatment of autoimmune diseases or severe skin or rheumatoid diseases)
- Corticosteroids (for treatment of inflammation, including conditions such as asthma and rheumatoid arthritis)
- Bepridil (for treatment of angina pectoris, a condition causing chest pain)
- Cisapride (used for treatment of reduced motility of the esophagus and stomach)
- Diphenamil (used for treatment of digestive system problems, such as ulcers, hyperacidity and hyperactivity of the digestive system)
- Sparfloxacin, moxifloxacin (antibiotics for treatment of infections)
- Halofantrine (for treatment of certain types of malaria)
- Mizolastine (for treatment of allergic reactions, such as hay fever)
- Iodine-containing contrast agents (used for x-ray tests)
- Calcium supplements

❗ Use of the medicine and food:

The medicine may be taken with no regard to meal times. Follow the doctor's instructions. Your doctor may instruct you regarding a daily exercise program and a low-salt or low-sodium diet, including potassium supplements and large amounts of potassium-rich foods (such as bananas, prunes, raisins and orange juice).

❗ Pregnancy, breastfeeding and fertility:

The medicine is not recommended for pregnant women. If you are pregnant or breastfeeding, might be pregnant, or are planning to become pregnant, consult the doctor before using the medicine. In case of pregnancy or if you plan to become pregnant, switch to an alternative therapy as soon as possible. Inform the doctor if you are pregnant or are planning to become pregnant.

The active ingredient is excreted into breastmilk. The medicine is not recommended for breastfeeding women.

❗ Driving and operating machinery:

Pamid may cause dizziness due to a drop in blood pressure. If this occurs, do not drive or operate dangerous machinery while using the medicine.

These effects usually occur in the beginning of the treatment or when the dosage is increased.

❗ Important information about some ingredients of the medicine:

This preparation contains lactose. If you have been told by the doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.

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 how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is one tablet per day, which should be taken in the morning.

Do not exceed the recommended dose.

The medicine should be swallowed with a glass of water. Do not chew. The tablet may be halved.

If you accidentally took a higher dose, you might suffer from nausea, vomiting, low blood pressure, cramps, dizziness, drowsiness, confusion and change in the amount of urine produced by the kidneys.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take the medicine on time, take the dose as soon as you remember, unless it is almost time to take the next dose. Do not take a double dose in order to compensate for the dose that you forgot to take.

Follow the treatment 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 or pharmacist.

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

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

4. Side effects:

As with any medicine, using Pamid may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not experience any of them.

Stop using this medicine and refer to a doctor immediately if you experience:

- Angioedema and/or hives. Angioedema is characterized by swelling of the skin in the limbs or face, swelling of the lips and tongue, swelling of the mucous membranes in the throat or airways, which may cause breathing or swallowing difficulties.
- Serious skin reactions, including severe rash, reddening of the skin all over the body, serious itching, blisters, exfoliation and swelling of the skin, inflammation of the mucous membranes (Stevens Johnson syndrome) or other allergic reactions.
- Irregular heartbeat, which may be life-threatening.
- Inflamed pancreas, which may cause severe pain in the abdomen and back and is accompanied by severe malaise.
- A brain disease caused by a liver disease (hepatic encephalopathy).
- Hepatitis.
- Allergic reactions, mainly of the skin, such as rash in patients with a tendency for allergic and asthmatic reactions.

Additional side effects:

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

- Maculopapular rash (raised red rash)

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

- Vomiting
- Purpura (red spots on the skin)

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

- Feeling of tiredness, headache, numbness, vertigo
- Gastrointestinal disturbances such as nausea or constipation, dry mouth

Very rare side effects - side effects that occur in less than one out of 10,000 patients:

- Changes in blood count, such as thrombocytopenia (a decrease in the number of platelets, which may cause bruises to occur more easily as well as nose bleeding), leukopenia (a decrease in white blood cells count, which may cause unexplained fever, sore throat or other flu-like symptoms) and anemia (a decrease in red blood cells count)
- Increased blood calcium levels
- Arrhythmias (which cause palpitations), low blood pressure
- Kidney problems (which cause fatigue, increased need to urinate, skin itching, nausea and limb swelling)
- Liver function impairment

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Fainting
- If you are suffering from systemic lupus erythematosus, the symptoms of the disease may worsen
- Sensitivity to light after exposure to sunlight or artificial UVA rays
- Nearsightedness (myopia)
- Blurry vision
- Visual impairment
- The medicine may cause changes in blood test results, which the doctor may want to monitor:
 - A decrease in blood potassium level
 - A decrease in blood sodium level, which may cause dehydration, a decrease in blood pressure
 - Elevated uric acid levels, which may cause or aggravate gout (sore joints, especially in the feet)
 - An increase in blood glucose level in diabetic patients
 - Rise in liver enzymes level
- Abnormal ECG
- Visual impairment or eye pain due to high pressure (possible signs of accumulation of fluids in the vascular layer of the eye (choroidal effusion) or acute closed-angle glaucoma)

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

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp.) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature lower than 25°C.
- Store in the original package.

6. Additional information:

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

Lactose, Maize Starch, Povidone, Stearic Acid, Hydroxypropylmethylcellulose, Titanium Dioxide, Propylene Glycol.

What does the medicine look like and what are the contents of the package:

A package containing 30 white, convex, film-coated tablets, scored on one side.

Manufacturer/license holder and address:

CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi.

This leaflet was revised in 02/2021 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 65-94-26489

