

## **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  
Inactive ingredients and allergens in the preparation – see the subsection "Important information about some of the 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 the treatment of hypertension and edema.

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

#### **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 from severe kidney failure.
- You have a severe liver disease or you suffer from hepatic encephalopathy (a liver problem that affects the brain and nervous system).
- You have a low level of potassium in the blood.

**❗ Special warnings regarding the use of the medicine:**

**Before treatment with Pamid, inform the doctor if:**

- You have a liver and/or kidney problem.
  - You have a heart rate problem.
  - You have diabetes.
  - You have gout (severe swelling and pain in the joints).
  - You have a parathyroid gland disease.
  - 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 an allergy to penicillin or sulfonamide.
  - You have muscle disorders, including muscle pain, tenderness, weakness or cramps.
- Tell your doctor if you have reactions associated with sensitivity to light.

**❗ Tests and follow-up:**

Your doctor may conduct blood tests to check for low potassium and sodium levels or high calcium levels. 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 interactions:**

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

- **Lithium.** Do not combine Pamid and lithium due to the risk of increased lithium levels in the blood
- Medicines for treatment of heart rhythm problems, such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, digitalis and bretylium
- Medicines used to treat mental disorders (depression, anxiety, schizophrenia), such as tricyclic antidepressants, antipsychotic medicines, neuroleptic medicines such as amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol, pimozide
- Bepridil (for treatment of angina pectoris, a condition causing chest pain)
- Cisapride (used for treatment of reduced motility of the esophagus and stomach)
- Diphemanil (used for treatment of digestive system problems, such as ulcers, hyperacidity and hyperactivity of the digestive system)
- Sparfloxacin, moxifloxacin, erythromycin by intravenous administration (antibiotics for treatment of infections)
- Vincamine by injection (for treatment of symptomatic cognitive disorders in the elderly, including memory loss)
- Halofantrine (for treatment of certain types of malaria)
- Pentamidine (for treatment of certain types of pneumonia)
- Antihistamines such as mizolastine, astemizole, terfenadine (for treatment of allergic reactions, such as hay fever)
- Non-steroidal anti-inflammatory drugs such as ibuprofen or high doses of salicylic acid
- ACE inhibitors (for treatment of hypertension and heart failure)
- Amphotericin B by injection (for treatment of fungal infections)
- Oral corticosteroids (for treatment of various conditions including severe asthma and rheumatoid arthritis)
- Stimulant laxatives (for treatment of constipation)
- Baclofen, which is a muscle relaxant (for treatment of muscle rigidity that occurs in diseases such as multiple sclerosis)
- Allopurinol (for treatment of gout)
- Potassium-sparing diuretics, such as amiloride, spironolactone, triamterene
- Metformin (for treatment of diabetes)
- Iodine-containing contrast agents (used for x-ray tests)

- Calcium supplements
- Immunosuppressants such as cyclosporine, tacrolimus (used to prevent organ rejection after organ transplantation, for treatment of autoimmune diseases or severe skin or rheumatoid diseases)
- Tetracosactide (for treatment of Crohn's disease)
- Methadone (for treatment of addictions)

**❗ Use of the medicine and food:**

The medicine may be taken with no regard to meal times.

**❗ Pregnancy, breastfeeding and fertility:**

The medicine is not recommended for use during pregnancy.

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 use while breastfeeding.

**❗ Driving and operating machinery:**

Pamid may cause dizziness or tiredness 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:**

The medicine 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 medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

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

If 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 a child accidentally swallowed this medicine, 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 this medicine at the required time, take the next dose at the regular time.** Do not take a double dose in order to compensate for the dose that you forgot to take.

**If you stop taking this medicine,** you should consult a doctor before stopping the treatment, as the treatment of high blood pressure is usually for life.

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 a medicine. Wear glasses if you need them.**

**If you have any other questions regarding the 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 of 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. (Very rare side effects).
- Serious skin reactions, including severe rash, reddening of the skin all over the body, severe itching, blisters, exfoliation and swelling of the skin, inflammation of the mucous membranes (Stevens Johnson syndrome) or other allergic reactions. (Very rare side effects).
- Irregular heartbeat, which may be life-threatening. (Unknown frequency).
- Inflamed pancreas, which may cause severe pain in the abdomen and back and is accompanied by severe malaise. (Very rare side effect).
- A brain disease caused by a liver disease (hepatic encephalopathy). (Unknown frequency).
- Inflammation of the liver (Hepatitis). (Unknown frequency).
- Muscle weakness, cramps, tenderness or pain, particularly if at the same time you have a fever or feel unwell. This may be caused by an abnormal muscle breakdown. (Unknown frequency).

**Additional side effects:**

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

- Red raised skin rash
  - Allergic reactions, mainly of the skin, such as rash, in patients with a tendency to allergic and asthmatic reactions
  - A decrease in blood potassium level
- Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
- Vomiting
  - Purpura (red spots on the skin)
  - A decrease in blood sodium level, which may cause dehydration and a decrease in blood pressure

- Impotence (inability to obtain or maintain an erection)

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
- A decrease in blood chloride level
- A decrease in blood magnesium level

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

- 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 cell count which may cause unexplained fever, sore throat or other flu-like symptoms – if this effect occurs, you should contact a doctor) and anemia (a decrease in red blood cells count)

- An increase in blood calcium level
- Arrhythmias (which cause palpitations and heart pounding), low blood pressure
- Kidney problems (causing fatigue, more frequent urination, itchy skin, nausea and swelling of the limbs)
- 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)
- Blurred vision
- Visual impairment
- The medicine may cause changes in blood test results, which the doctor may want to monitor:
  - 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
  - A rise in liver enzyme 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](http://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 below 25°C.
- Store in the original package to protect from light.

#### **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.

**Name of manufacturer/marketing authorization holder and address:** CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was revised in 07/2022 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

