# AMILOZIDE TABLET

Amiloride Hydrochloride/Hydrochlorothiazide (5mg/50mg)

**What is in this leaflet**

1. What AMILOZIDE is used for
2. How AMILOZIDE works
3. Before you use AMILOZIDE
4. How to use AMILOZIDE
5. While you are using it
6. Side effects
7. Storage and Disposal of AMILOZIDE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

**What AMILOZIDE is used for**

AMILOZIDE is used to treat:

- High blood pressure (alone or in combination with other medicines).
- Swelling due to excess fluid in body which caused by heart problem.
- Excess fluid in the abdomen, related to liver problem.

**How AMILOZIDE works**

AMILOZIDE contains two active ingredients which are amiloride hydrochloride and hydrochlorothiazide. The combination of amiloride/hydrochlorothiazide helps reduce the amount of excess fluid in the body by increasing the amount of urine produced, while at the same time minimizing potassium loss. This helps reduce blood pressure and swelling.

**Before you use AMILOZIDE**

*- When you must not use it*

Do not take this medicine if you have/are:

- Allergic to amiloride, hydrochlorothiazide, sulphonamide or any sulphur medicines or any other ingredients of this medicine (listed in Product Description).
- High potassium in blood or taking other medicines/supplements that causes high potassium.
- High calcium in blood.
- Severe kidney or liver impairment.
- Nerve problem related to diabetes.
- Addison's disease (adrenal glands disorder).
- Taking spironolactone or triamterene (medicines for excess fluid in the body).
- Taking lithium (medication to treat certain mental illnesses).

The safety of amiloride hydrochloride for use in children under 18 years of age has not been established.

If you are pregnant, planning to get pregnant or think you may be pregnant, discuss with your doctor before starting any medicine.

AMILOZIDE is not recommended during pregnancy, as it crosses the placenta and its use after the third month of pregnancy may potentially cause harm to your baby.

AMILOZIDE is not recommended to be used in breastfeeding mothers since fluid loss may inhibit milk production. Discuss with your doctor about the best way to feed your baby.

*- Before you start to use it*

Tell your doctor if you have:

- Kidney or liver problems.
- Heart or lung problems.
- High cholesterol.
- Gout.
- Diabetes and taking medicines for diabetes, including insulin.
- Severe asthma.
- Immune related disorder such as systemic lupus erythematosus.
- Genetic disorders of intolerance to certain glucose.
- Had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking AMILOZIDE.
- Experience breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking AMILOZIDE, seek medical attention immediately.

*- Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket, or health food shop.

Some medicines and AMILOZIDE may interfere with each other. These include:

- Medicines used to treat kidney cancer such as aldesleukin.
- Non-steroidal anti-inflammatory drugs (NSAIDS) or pain reliever used to reduce fever, pain, or inflammation.
- Medicines used to lower cholesterol e.g., cholestyramine, colestipol.
- Medicines used to treat abnormal heart rhythms e.g., quinidine.
- Trimethoprim (medicines used to treat bacterial infections).
- Medicines to treat depression (e.g., reboxetine, barbiturates, tricyclic antidepressants, and monoamine oxidase inhibitors (MAOIs)).
- Antidiabetics medicines, including insulin.
- Antiepilepsy such as carbamazepine.
- Amphotericin and fluconazole, used to treat fungal infections.
- Allopurinol, used to treat gout.
- Astemizole and terfenadine (medicine to treat allergy).
- Medicines used to treat high blood pressure such as prazosin, hydralazine. AMILOZIDE should be discontinued for 2-3 days before starting treatment with certain antihypertensive.
- Medicines used to treat malaria, such as halofantrine.
- Pimozide, sertindole, phenothiazines, lithium, medicines for mental conditions.
- Supplements or medicines containing calcium, vitamin D and potassium.
- Cardiac glycoside and nitrates, medicines used in heart failure.
- Corticosteroids, an anti-inflammatory medicine such as cortisone and hydrocortisone.
- Diuretics such as spironolactone, triamterene, or acetazolamide.
- Amantadine, levodopa, medicines used to treat Parkinson's disease.
- Hormones or medicines acting on hormones (e.g., trilostane, toremifene, oestrogens).
- Ciclosporin and tacrolimus, medicines used to prevent rejection following organ transplant.
- Tizanidine and tubocurarine, medicines to relax muscle during injury or surgery.
- Alcohol and medicines containing alcohol.
- Alprostadil, medicines to treat erectile dysfunction.
- Carbenoxolone, medicine to treat ulcer.

# AMILOZIDE TABLET

Amiloride Hydrochloride/Hydrochlorothiazide (5mg/50mg)

Other medicine not listed above may also interact with AMILOZIDE. Your pharmacist or doctor will have more information on the medicines you should avoid.

**How to use AMILOZIDE**
Take your medication exactly as directed by your doctor.

*- How much to use*
Your doctor will determine your dose based on your diagnosis and response.

Your initial dose may be maintained or adjusted until your condition is under control, but not more than 4 tablets every day.

*Elderly and people with kidney problems:*
Your doctor will adjust the dose according to your condition.

*- When to use it*
If you are taking once a day, take it in the morning.

If you are taking a few times a day, take the last dose in the early evening, unless your doctor tells you otherwise.

AMILOZIDE may increase the amount of urine you pass and the number of times you go to the toilet.

By taking the last dose in the early evening there may be less chance of your sleep being disturbed.

Take AMILOZIDE at about the same time each day, unless your doctor tells you otherwise. This will help you remember when to take the tablets.

*- How long to use it*
Take AMILOZIDE for the duration that the doctor recommends.

*- If you forget to use it*
Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

*- If you use too much (overdose)*
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the carton or any remaining tablets you have with you.

Taking too many tablets may cause dehydration (loss of too much fluid from the body), low blood pressure and electrolyte imbalance.

**While you are using it**
*- Things you must do*
Tell all the doctors, dentists and pharmacists treating you that you are taking AMILOZIDE.

Tell your doctor immediately if you become pregnant while using this medication.

Take AMILOZIDE only with a doctor's prescription.

*- Things you must not do*
Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give AMILOZIDE to anyone else, even if they have the same symptoms or condition as you.

*- Things to be careful of*
- Hydrochlorothiazide is a sulphur containing medicine (a sulphonamide). Therefore, if you are allergic to sulphur medicines, such as some antibiotics, you are likely to be allergic to AMILOZIDE.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking AMILOZIDE. It may affect other medicines used during surgery.
- If you are about to have any blood tests or x-rays, tell your doctor that you are taking AMILOZIDE. It may interfere with the results of some tests.

*Driving and using machines*
This medicine may affect your ability to drive or use machines. If the tablets make you feel dizzy, tired, visual problems, headache or became unresponsive and feeling of spinning motion, do not drive or use machines and contact your doctor immediately.

**Side effects**
Like all medicines, AMILOZIDE can cause side effects, although not everybody gets them.

Tell your doctor as soon as possible if you notice any of the following:
- severe allergic reaction such as breathing difficulties, light headedness, skin swellings or rash;
- appetite changes;
- increase potassium levels, low sodium levels;
- sleeping difficulty, nervousness;
- headache, dizziness, sleepiness, faint, tingling or pricking sensation;
- vision problem;
- feeling of spinning motion;
- irregular heartbeat, chest pain, heart block;
- nausea, vomiting, diarrhoea, constipation, abdominal pain, gastrointestinal bleeding, bloated or gassy stomach;
- rash, itching, excessive sweat;
- leg ache, muscle cramps, joint or back pain;
- loss of bladder control, kidney problem;
- low blood cell counts, inflammation of the blood vessel walls;
- cough;
- hair loss;
- infections of the salivary gland;
- lung inflammation or excessive fluid in the lung;
- pancreas inflammation.

Frequency very rare:
- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

Frequency 'not known':
- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes.
- Acute myopia: sudden near-sightedness or blurred vision.

# AMILOZIDE TABLET

Amiloride Hydrochloride/Hydrochlorothiazide (5mg/50mg)

- Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.
- Skin and lip cancer (non-melanoma skin cancer).

Tell your doctor or pharmacist if you notice anything else that make you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of AMILOZIDE**

*- Storage*

Keep medicines in original packaging. Do not store above 30°C. Store in dry place, away from direct heat and light and excessive moisture. Do not leave your medicine in the car.

Keep all medicines out of the reach of children.

*- Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your doctor and pharmacist how to dispose of medicines.

**Product Description**

*- What it looks like*

AMILOZIDE Tablet is an orange rhombus biconvex tablet.

*- Ingredients*

- Active ingredients

  Each tablet contains 5 mg of Amiloride hydrochloride and 50 mg of Hydrochlorothiazide.

- Inactive ingredients

  Lactose monohydrate, corn starch, pregelatinize starch, sodium starch glycolate, talc, magnesium stearate, polysorbate 80, sunset yellow (colouring).

*- MAL number:*

MAL09072804AZ

**Manufacturer**

T.O. Chemicals (1979) Ltd.
280 Soi Sabaijai, Suthisarnwinijai Road,
Samsennok, Huay-Kwang,
Bangkok 10310, Thailand.

**Product Registration Holder**

IMEKS Pharma Sdn. Bhd.
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Medan Niaga Kepong
51200 Kuala Lumpur, Malaysia.

**Date of revision**

27/08/2025

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