Hydrochloorthiazide 12,5 mg 25mg, tablets

What is Hydrochloorthiazide and what is it used for?
Hydrochloorthiazide contains the active ingredient hydrochloorthiazide, which belongs to a group of medicines called "diuretics." Diuretics increase the amount of urine produced by the kidneys and are sometimes called water tablets.

Hydrochloorthiazide 12.5 mg and 25 mg is used to treat:

- high blood pressure (essential arterial hypertension)
- fluid retention in tissues due to heart, liver, or kidney disease (cardiac, hepatic, or renal edema)

When should you not use this medicine or take extra caution?

When should you not use this medicine?

- You are allergic to hydrochloorthiazide, other thiazides or sulfonamides, or any of the other ingredients of this medicine. These substances can be found in section 6.
- You have severe kidney problems.
- You have acute kidney inflammation (glomerulonephritis).
- You have severe liver problems, such as liver failure with decreased consciousness.
- You have low potassium levels in your blood (hypokalemia).
- You have low sodium levels in your blood (hyponatremia).
- You have decreased blood volume (hypovolemia).
- You have elevated calcium levels in the blood (hypercalcemia).
- You have elevated uric acid levels in the blood (hyperuricemia) causing symptoms (patients with a family history of gout).
- You suffer from gout.
- You have high blood pressure during pregnancy.

When should you take extra caution with this medicine?

Contact your doctor or pharmacist before using this medicine if:

- You have experienced respiratory or lung problems (including inflammation or fluid in the lungs) after taking hydrochloorthiazide in the past. If you experience severe shortness of breath or difficulty breathing after taking this medicine, seek immediate medical assistance.
- You have had skin cancer or if you develop a suspicious skin lesion during treatment. Treatment with hydrochloorthiazide, especially prolonged use with high doses, may increase the risk of certain types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from exposure to the sun and UV rays while using this medicine.
- You have severely low blood pressure (hypotension).
- You have problems with the blood vessels in your brain or the blood vessels that supply blood to your brain.
- You have a heart condition due to abnormalities in the coronary arteries (coronary heart disease).
- You have diabetes.
- You have other kidney problems (including a kidney transplant).
- You have other liver problems.
- You experience reduced vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or increased pressure in your eye that can occur within hours to a week after taking this medicine.
- You have asthma.
- You have Addison's disease.
- You are elderly.

If you have low potassium, sodium, or magnesium levels in your blood or reduced blood circulation, your doctor will treat these conditions before prescribing Hydrochloorthiazide Mylan. Your doctor may also perform regular blood tests to monitor salt, sugar, fat, creatinine, urea, or uric acid levels.

Make sure to drink sufficient amounts of fluids. Due to increased potassium loss, you should consume foods rich in potassium (such as bananas, vegetables, nuts).

If you need to undergo surgery, inform your doctor, nurse, or dentist that you are using this medicine.

Children and adolescents under 18 years of age: There is no experience with this medicine in children and adolescents under 18 years of age. Therefore, this medicine should not be administered to children and adolescents under 18 years of age.

Are you taking any other medicines?
In addition to Hydrochloorthiazide Mylan, are you using any other medicines now or have you recently done so, or are you likely to use other medicines in the near future? Inform your doctor or pharmacist about this. This applies particularly to the following products:

- Medicines associated with potassium loss and deficiency in the blood, other diuretics (such as other thiazides, sulfonamides), kaliuretic diuretics (such as furosemide), glucocorticoids, ACTH, laxatives, carbenoxolone, amphotericin B, sodium penicillin G, salicylic acid, and derivatives.
- Lithium, barbiturates, phenothiazines, or tricyclic antidepressants used in the treatment of depression.

- Blood pressure-lowering medications (such as guanethidine, methyldopa, calcium antagonists, ACE inhibitors like captopril or enalapril, angiotensin receptor blockers (ARBs), direct renin inhibitors (DRRs), beta blockers, diazoxide, nitrates, vasodilators).
- Salicylates and other non-steroidal anti-inflammatory drugs (e.g., indomethacin), including selective COX-2 inhibitors.
- Insulin or oral antidiabetic drugs (e.g., metformin) used for the treatment of high blood sugar levels.
- Medicines used for the treatment of gout (e.g., allopurinol, probenecid, sulfinpyrazone).
- Norepinephrine used to treat low blood pressure.
- Epinephrine used to treat severe allergic reactions.
- Cardiac glycosides (e.g., digitoxin) used to treat heart failure.
- Cytostatics (e.g., cyclophosphamide, fluorouracil, methotrexate) used as chemotherapy in cancer treatment.
- Curare-type muscle relaxants (e.g., pancuronium).
- Cholestyramine or colestipol used to lower cholesterol levels in the blood.

Medicines affected by disturbances in blood potassium levels:

- Antiarrhythmics of class Ia (e.g., quinidine, hydroquinidine, disopyramide);
- Antiarrhythmics of class III (e.g., amiodarone, sotalol, dofetilide, ibutilide);
- Certain antipsychotics (e.g., thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, sultopride, amisulpride, tiapride, pimozide, haloperidol, droperidol);
- Other medications (e.g., bepridil, cisapride, diphemanil, erythromycin IV, halofantrine, mizolastine, pentamidine, sparfloxacin, terfenadine, vincamine IV).
- Amantadine used to treat Parkinson's disease.
- Calcium supplements.
- Vitamin D supplements.
- Cyclosporine used after transplantation.
- Carbamazepine used to treat epilepsy and nerve pain.
- Quinidine used to treat heart problems.
- Tetracyclines, a group of antibiotics used to treat infections.

What should you be aware of regarding alcohol?
Do not consume alcohol during treatment as it can increase the effects of this medication.

Pregnancy and breastfeeding: Consult your doctor or pharmacist before taking any medication.

Pregnancy: If you are pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding, contact your doctor or pharmacist before using this medication.

Your doctor will usually advise you to use another medication because the use of this medication is not recommended during pregnancy. This is because hydrochlorothiazide crosses the placenta and can have adverse effects on your baby during the second and third trimesters of pregnancy.

Breastfeeding: Inform your doctor if you are breastfeeding or planning to start breastfeeding. This medication is not recommended for breastfeeding mothers.

Driving and using machinery: This medication has a minor or moderate influence on driving ability and the use of machinery.

This is particularly true at the beginning of treatment or when the dose is increased. Do not operate vehicles or machinery if you experience these effects.

Hydrochloorthiazide contains lactose.

This medication contains lactose (milk sugar). If your doctor has informed you that you are intolerant to certain sugars, contact your doctor before taking this medication.

How to use this medication?
Always use this medication exactly as your doctor or pharmacist has instructed you. If you are unsure about the correct usage, contact your doctor or pharmacist.

Hydrochloorthiazide is available in 3 dosages: tablets of 12.5 mg, 25 mg, and 50 mg.

High blood pressure (essential arterial hypertension):

- The recommended initial dose is one or two hydrochlorothiazide tablets of 12.5 mg per day or half or one hydrochlorothiazide tablet of 25 mg per day (12.5 - 25 mg hydrochlorothiazide per day).
- The recommended long-term dose is usually one hydrochlorothiazide tablet of 12.5 mg per day or half a hydrochlorothiazide tablet of 25 mg per day (12.5 mg hydrochlorothiazide per day).

Heart, liver, and kidney edema:

- The initial dose is 25 mg or 50 mg of hydrochlorothiazide per day.
- The long-term dose is usually 25 mg to 100 mg of hydrochlorothiazide per day.

Patients with impaired kidney or liver function: In case of mild to moderate kidney or liver dysfunction, the dose of hydrochlorothiazide should be adjusted according to the impairment.

Patients with severe cardiac decompensation: In patients with excessive fluid retention due to a weak heart muscle (severe cardiac decompensation), the absorption of hydrochlorothiazide may be significantly reduced.

Children and adolescents under 18 years of age: There is no experience with children and adolescents under 18 years of age. Therefore, hydrochlorothiazide should not be administered to children and adolescents under 18 years of age.

Method of administration:

- The tablets should be taken with breakfast without chewing and with an ample amount of liquid.
- 12.5 mg tablet: The score line is there to break the tablet if you have difficulty swallowing the whole tablet.
- 25 mg tablet: The tablet can be divided into equal doses.

Duration of treatment:

The duration of treatment is unlimited and depends on the type and severity of the disease. If you want to stop using this medication, first contact your doctor (see "If you stop using this medication")

After long-term treatment, the treatment with this medication should be gradually discontinued.

Contact your doctor or pharmacist if you think the effect of Hydrochloorthiazide is too strong or too weak.

Have you used too much of this medication?
If you have taken more tablets than you should, you should immediately inform your doctor. He or she will decide what measures need to be taken based on the symptoms. In case of poisoning and/or severe symptoms, immediate medical treatment is required.

You may experience the following: thirst, a feeling of weakness and dizziness, muscle pain and muscle cramps (e.g., calf cramps), headache, circulatory disturbances with an accelerated heartbeat, and lower blood pressure when transitioning from a lying to a standing position. Additionally, seizures, drowsiness (lethargy), confusion, transient loss of consciousness due to reduced blood flow to the brain (circulatory collapse), and acute kidney failure may occur.

You may also experience fatigue, muscle weakness, sensations of tingling, itching or tingling without apparent cause (sensory disturbances), paralysis, lack of interest, flatulence, constipation, or cardiac arrhythmias, intestinal obstruction, decreased consciousness, or unconsciousness.

Have you forgotten to use this medication: Do not take a double dose to make up for a missed dose, but continue the treatment with the prescribed dose.

If you stop using this medication: You should not interrupt or stop the treatment with hydrochlorothiazide without consulting your doctor first.

Possible side effects

Like all medications, this medication can have side effects, although not everyone experiences them.If you experience any of the following side effects, stop using this medication immediately and contact your doctor or go to the nearest emergency department:

Common (occur in less than 1 in 10 users): Reduction in the number of platelets, leading to bleeding or bruising more easily, possibly with a rash of purple spots (thrombocytopenia, sometimes with purpura).

Uncommon (occur in less than 1 in 100 users): Increased susceptibility to infections, such as fever, severe chills, sore throat, and mouth ulcers. These may be signs of low levels of white blood cells (leukopenia or agranulocytosis).

Inflammation of the pancreas (pancreatitis).

Production of urine with flakes or dark urine. These may be signs of kidney disease (interstitial nephritis).

Shortness of breath. You may experience a cough that produces colorless mucus (acute interstitial pneumonitis) and fluid buildup in the lungs (pulmonary edema).

Yellowing of the skin and whites of the eyes, pale stools, dark urine, and itching in pregnant women (intrahepatic cholestasis).

Rare (occur in less than 1 in 1000 users): Anaphylactic reaction, for example, sudden signs of allergy such as rash, itching, or hives on the skin (anaphylactic reaction);

- Swelling of the face, lips, tongue, throat, or other parts of the body that can cause wheezing or difficulties with breathing or swallowing.
- Very rare (occur in less than 1 in 10,000 users):
- Sudden shortness of breath (symptoms include severe shortness of breath, fever, weakness, and confusion);
- Severe skin reactions such as blisters, skin detachment, or widespread rash (toxic epidermal necrolysis, cutaneous lupus erythematosus, lupus erythematosus-like reactions, reactivation of lupus erythematosus, erythema multiforme);
- Severe decrease in blood cells, which can cause weakness, bleeding, and infections (aplastic anemia);
- Decrease in red blood cells, which can result in pale skin and weakness or shortness of breath (hemolytic anemia);
- Disintegration of red blood cells (immune hemolytic anemia) due to antibody formation when used concurrently with methyldopa.

Other possible side effects include:

Very common (occur in more than 1 in 10 users):

- Disturbances in electrolyte and fluid balance, particularly decreased potassium, sodium, and chloride levels and increased calcium levels in the blood (hypokalemia, hyponatremia, hypochloremia, and hypercalcemia);
- Increased blood sugar levels (hyperglycemia) and increased sugar excretion in the urine (glucosuria) in individuals with a healthy metabolism;
- Patients in the early stages of diabetes mellitus (latent diabetes mellitus) or in diabetic patients and patients with potassium deficiency;
- Increased blood uric acid levels (hyperuricemia), which can lead to gout attacks in predisposed patients;
- Increase in blood lipids (cholesterol, triglycerides), which may be seen in a blood test;
- Increased sugar levels in the urine (glucosuria), which may be seen in a urine test.
- Common (occur in less than 1 in 10 users):
- Palpitations (heart palpitations);
- Decreased appetite, gastrointestinal complaints (e.g., nausea, vomiting, diarrhea, abdominal pain, and cramps);
- Temporary increase in blood creatinine levels or urea levels in the urine;
- Decreased magnesium levels in the blood, which may be seen in a blood test (hypomagnesemia);
- Increased magnesium levels in the urine, which may be seen in a urine test (hypermagnesiuria);
- Inability to achieve or maintain an erection (impotence);
- Circulatory disorders with low blood pressure when changing from a lying to a standing position (orthostatic regulatory disorders), especially in patients with reduced blood volume.

(Intravascular volume depletion), such as in patients with severe heart failure or patients treated with a high dose of diuretics.

Sometimes (occur in less than 1 in 100 users):

- Visual disturbances (e.g., blurred vision, color vision changes (yellow vision), limited tear production, worsening of nearsightedness (myopia);
- Inflammation of blood vessels, often with rash (vasculitis);
- Increased levels of a specific liver enzyme (amylase) in the blood (hyperamylasemia), jaundice (icterus);
- Other allergic skin reactions (such as itching, redness of the skin, rash due to sensitivity to light or sunlight (photoallergic exanthem), purple or reddish-brown spots caused by bleeding or bruising on the skin (purpura), itchy hives (urticaria);
- Impotence;
- Fever (possibly caused by an allergic reaction to the medication);
- Increased magnesium levels in the urine (hypermagnesiuria).

Rare (occur in less than 1 in 1,000 users):

- Sleep disorders, depression;
- Headache, dizziness, tingling or numbness in the arms or legs (paresthesia);
- Changes in heart rhythm (arrhythmias);
- Constipation;
- Worsening of eye vision, especially in the first few weeks of treatment.

Very rare (occur in less than 1 in 10,000 users):

- Decrease in the number of blood cells (bone marrow depression);
- When the body produces excessive amounts of acid or when the kidneys do not remove enough acid (hypochloremic alkalosis).

- Unknown (based on available data, the frequency cannot be determined):
- Worsening of symptoms in patients with existing diabetes (manifest diabetes mellitus) such as sweating, trembling, and increased appetite.
- Development of symptoms in people developing diabetes (latent diabetes mellitus) such as increased hunger, thirst, and urination;
- Other kidney problems;
- Muscle cramps;
- Feeling weak;
- Blood clotting (thrombosis) or sudden blockage of a blood vessel (embolism) in patients or elderly patients with thickened blood (hemoconcentration) of vascular diseases.

How to store this medicine?

- Keep out of the sight and reach of children.
- There are no special storage conditions for this medicine.
- Do not use this medicine after the expiry date stated on the box or blister after "EXP:". The expiry date refers to the last day of that month.
- Do not dispose of medications in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.