

Package leaflet: Information for the patient
Hydrochlorothiazide Mylan 12.5 mg, tablets
Hydrochlorothiazide Mylan 25 mg, tablets
Hydrochlorothiazide

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet:

1. What is Hydrochlorothiazide Mylan and what is it used for?
2. When should you not use this medicine or be extra careful?
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1. What is Hydrochlorothiazide Mylan and what is it used for?

Hydrochlorothiazide Mylan contains the active substance hydrochlorothiazide, 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.

Hydrochlorothiazide Mylan 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 (heart, liver, or kidney edema).

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to hydrochlorothiazide, other thiazides or sulfonamides, or any of the other ingredients in this medicine. You can find these ingredients in section 6.
- You have severe kidney problems.
- You have an acute kidney inflammation (glomerulonephritis).
- You have severe liver problems, such as liver failure with reduced consciousness.
- You have low potassium levels in your blood (hypokalemia).
- You have low sodium levels in your blood (hyponatremia).
- You have a reduced blood volume (hypovolemia).
- You have an increased calcium level in the blood (hypercalcemia).
- You have an increased uric acid level in the blood (hyperuricemia) that causes symptoms (patients with a family history of gout).
- You suffer from gout.

- You have high blood pressure during pregnancy.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you have previously experienced breathing or lung problems (including inflammation or fluid in the lungs) after taking hydrochlorothiazide. If you experience severe shortness of breath or difficulty breathing after taking this medicine, seek medical help immediately;
- if you have had skin cancer or if you develop a suspicious skin lesion during treatment. Treatment with hydrochlorothiazide, especially long-term 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;
- if you have severely low blood pressure (hypotension);
- if you have problems with the blood vessels in your brain or the blood vessels supplying your brain with blood;
- if you suffer from a heart condition due to abnormalities in the coronary arteries (coronary heart disease);
- if you have diabetes;
- if you have other kidney problems (including a kidney transplant);
- if you have other liver problems;
- if you experience reduced vision or eye pain. These may 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.
- when you have asthma;
- when you have Addison's disease;
- when you are an older adult.

When you have low potassium, sodium, or magnesium levels in your blood or a reduced blood circulation, your doctor will first treat you for this before you receive Hydrochlorothiazide Mylan. It may happen that your doctor regularly checks your blood (for example, to monitor the salt, sugar, fat, creatinine, urea, or uric acid levels). Make sure you drink sufficient amounts of fluid. Due to the increased loss of potassium, you should consume foods rich in potassium (such as bananas, vegetables, nuts). When you need to undergo surgery, inform your doctor, nurse, or dentist that you are using this medicine. used.

There is no experience in children and adolescents up to 18 years. Therefore, this medicine should not be administered to children and adolescents up to 18 years. Are you using any other medicines?

Are you using any other medicines besides Hydrochlorothiazide Mylan, or have you done so recently

or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This is especially important for the following products: Tell your doctor or pharmacist. This is especially true for the following products:

- Medicines associated with potassium loss and deficiency in the blood, others diuretics (e.g., other thiazides, sulfonamides), kaliuretic diuretics (e.g., 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.
- antihypertensive drugs (e.g., guanethidine, methyl dopa, calcium antagonists, ACE inhibitors such as captopril or enalapril, angiotensin receptor blockers (ARBs), direct renin inhibitors (DRIs), beta-blockers, diazoxide, nitrates, vasodilators).
- Salicylates and other non-steroidal anti-inflammatory drugs (e.g., indomethacin), including selective COX-2 inhibitors.
- Insulin or oral antidiabetics (e.g., metformin) used for the treatment of high blood sugar levels.
- drugs 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 treatment of cancer.
- muscle relaxants of the curare type (e.g., pancuronium)
- cholestyramine or colestipol used to lower cholesterol levels in the blood
- Medicines affected by disturbances in blood potassium levels:
 - anti-arrhythmics of class Ia (e.g., quinidine, hydroquinidine, disopyramide);
 - class III anti-arrhythmics (e.g., amiodarone, sotalol, dofetilide, ibutilide);
 - certain antipsychotics (e.g., thioridazine, chlorpromazine,
- levomepromazine, trifluoperazine, cyamemazine, sulpiride, sultopride, amisulpride, tiapride, pimozide, haloperidol, droperidol);
 - other agents (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
- ciclosporin 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 with alcohol?

Do not drink alcohol during treatment as it may enhance the effects of this medicine.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Usually, your doctor will advise you to use another medicine, as the use of this medicine is not recommended during pregnancy. The reason for this is that hydrochlorothiazide crosses the placenta and its use during the second and third trimesters of pregnancy can have adverse effects on your baby. have.

Breastfeeding

Tell your doctor if you are breastfeeding or planning to start. This medicine is not recommended for mothers who are breastfeeding.

Driving and using machines

This medicine has a minor or moderate influence on the ability to drive and use machines. This is especially true at the start of treatment or when the dose is increased. Do not drive vehicles or operate machines if you experience this

Hydrochlorothiazide Mylan contains lactose

This medicine contains lactose (milk sugar). If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine..

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Hydrochlorothiazide Mylan 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 hydrochlorothiazide per day.

The long-term dose is usually 25 mg to 100 mg 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 to the dysfunction.

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

Children and adolescents up to 18 years:

There is no experience in children and adolescents up to 18 years. Therefore, hydrochlorothiazide should not be administered to children and adolescents up to 18 years.

Method of administration

The tablets should be taken at breakfast without chewing with a generous 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

Duration of treatment

wish to stop using this medicine, first contact your doctor (see under "If you stop using this medicine") After long-term treatment, the treatment with this medicine should be gradually discontinued.

Contact your doctor or pharmacist if you think that the effect of Hydrochlorothiazide Mylan is too strong or too weak. Have you used too much of this medicine?

If you have taken more tablets than you should, you must inform your doctor immediately. He or she will decide what measures need to be taken based on the bring. He or she will decide which 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 increased heart rate, and a lower blood pressure when moving from a lying to a standing position. Additionally, seizures/convulsions, drowsiness (lethargy), confusion, short-term unconsciousness that resolves on its own and is caused by reduced blood flow to the brain (circulatory collapse) and acute kidney failure may occur. You may also experience fatigue, muscle weakness, perception of tingling, itching, or tingling without any cause (sensory disturbances), paralysis, disinterest, flatulence (flatulence) and constipation (obstipation) or arrhythmias, intestinal obstruction, reduced consciousness or unconsciousness.

Did you forget to use this medicine?

Do not take a double dose to make up for a forgotten dose, but continue the treatment with the prescribed dose.

If you stop using this medicine

You should not interrupt or stop the treatment with hydrochlorothiazide without first consulting your doctor. consultation. Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. experiencing.

If you experience any of the following side effects, stop using this medicine and contact your doctor immediately or go straight to the emergency department of the nearest hospital:

Common (affects less than 1 in 10 users):

- reduction in the number of platelets causing bleeding or bruising more easily than normal, possibly with a rash with purple spots (thrombocytopenia, sometimes with purpura);
- Uncommon (affects less than 1 in 100 users):

an increase in the number of infections you get such as fever, severe chills, sore throat, and

- mouth ulcers. These may be signs of low white blood cell levels (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).
- nephritis).
- shortness of breath (dyspnea). You may experience a cough that produces uncolored mucus (acute interstitial pneumonia) and accumulation of fluid in the lungs (pulmonary edema);

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

Rare (occur in less than 1 in 1,000 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 difficulty breathing or swallowing.

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

- sudden onset of breathlessness (symptoms include severe shortness of breath, fever, weakness, and confusion);
- severe skin reactions such as blisters, peeling of the skin, or widespread rash (toxic epidermal necrolysis, cutaneous lupus erythematosus, lupus erythematosus-like reactions, reactivation of a 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 cause pale skin and weakness or shortness of breath (hemolytic anemia);
- disintegration of red blood cells (immuno-hemolytic anemia) as a result of the formation of antibodies when used concurrently with methyldopa.

Not known (based on available data, the frequency cannot be established):

- Reduced vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute narrow-angle glaucoma);
- Producing little or no urine with pain in the lower back. These may be signs of severe kidney problems (acute kidney failure);
- An acute inflammation of the gallbladder (cholecystitis) may occur in cases of existing gallstones (cholelithiasis);
- Skin and lip cancer (non-melanoma skin cancer).

Other possible side effects include:

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

- disorders in the salt and fluid balance, particularly a decreased potassium, sodium, and chloride level and an increased calcium level in the blood (hypokalemia, hyponatremia, hypochloremia, and hypercalcemia);
- an increased blood sugar level (hyperglycemia) and increased excretion of sugar in the urine (glucosuria) in individuals with a healthy metabolism;
- patients in an early stage of diabetes mellitus (latent diabetes mellitus) or in diabetic patients and patients with potassium deficiency;
- an increased level of uric acid in the blood (hyperuricemia), this can lead to gout attacks in patients who are predisposed to it;
- an increase in blood lipids (cholesterol, triglycerides), which can be seen in a blood test;
- increased sugar levels in the urine (glucosuria), which can be seen in a urine test.

Common (occur in less than 1 in 10 users):

- palpitations;
- reduced appetite, gastrointestinal complaints (e.g., nausea, vomiting, diarrhea, abdominal pain and cramps);
- temporary increase in creatinine levels in the blood or urea levels in the urine;
- Decreased magnesium levels in the blood, which can be seen in a blood test (hypomagnesemia);
- Increased magnesium levels in the urine, which can be seen in a urine test (hypermagnesiuria);
- The inability to get or maintain an erection (impotence);
- circulatory disorders with decreased blood pressure when changing from a lying to a standing position (orthostatic regulation 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, seeing colors (yellow vision), limited tear production, worsening of nearsightedness (myopia); inflammation of blood vessels, often with a rash (vasculitis);
- inflammation of blood vessels, often with rash (vasculitis);
- elevated levels of a certain liver enzyme (amylase) in the blood (hyperamylasemia), jaundice (icterus);
- other allergic skin reactions (e.g., 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 under the skin (purpura), itchy hives (urticaria);
- impotence;
- fever (possibly caused by an allergic reaction to the medication);
- elevated 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);
- heart rhythm changes (arrhythmias);
- constipation (obstipation);
- deterioration of 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.
- Onset 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) from blood vessel diseases.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (website: www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. 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. You can find it on the box or blister after "EXP:". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medications down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medications you no longer use. They are then destroyed in a responsible manner and do not end up in the environment.

6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is hydrochlorothiazide. One tablet contains 12.5 mg or 25 mg hydrochlorothiazide.
- The other substances in this medicine are: lactose monohydrate, colloidal anhydrous silica, corn starch, and magnesium stearate.

What does Hydrochlorothiazide Mylan look like and how much is in a package?

Hydrochlorothiazide Mylan 12.5 mg tablets are white, round tablets with a score line on one side.

Hydrochlorothiazide Mylan 25 mg tablets are white, round tablets with a score line on one side.

Hydrochlorothiazide Mylan is available in blister packs of 10, 20, 30, 50, 90, 98, and 100 tablets.

Hydrochlorothiazide Mylan 12.5 mg and 25 mg tablets are also available in round, plastic tablet containers of 500 tablets.

Not all mentioned pack sizes are marketed.

This medicine is registered under number:

RVG 112547 – Hydrochlorothiazide Mylan 12.5 mg, tablets

RVG 112548 – Hydrochlorothiazide Mylan 25 mg, tablets

Marketing authorization holder and manufacturer

Marketing authorization holder

Mylan B.V.

Krijgsman 20

1186 DM Amstelveen

Manufacturer release

G.L.Pharma GmbH, Schlossplatz 1, A-8502 Lannach, Austria

This medicine is registered in EEA member states under the following names:
Netherlands Hydrochlorothiazide Mylan 12.5 mg/25 mg, tablets
This leaflet was last approved in June 2022.

Other sources of information

More information about this medicine is available on the website of the Medicines Evaluation Board
www.cbg-meb.nl

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