

PACKAGE LEAFLET: INFORMATION FOR THE USER

MONOZID

25 mg tablets

HYDROCHLOROTHIAZIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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1. WHAT MONOZID 25 IS AND WHAT IT IS USED FOR

MONOZID 25 is a medicine that lowers blood pressure and reduces swelling (edema) of different origin.

MONOZID 25 is a medicine that is used to eject water, sodium and chloride from the body, which leads to a decrease in blood pressure and edema. Monozid 25 lowers blood pressure in the standing and lying position, while its effect is not manifested on normal blood pressure.

Monozid 25 is used in the following cases:

- Mild to moderate hypertension (high blood pressure),
- Edema of different origin.

2. BEFORE YOU TAKE MONOZID

Inform the doctor if you are taking other medicines, have a chronic disease, a disorder of metabolism, if you are over sensitive to medication or have had an allergic reaction to some of them.

Do not take MONOZID 25:

- case of hypersensitivity to hydrochlorothiazide or any other substance (see section 6)
- case of the thiaside hypersensitivity to other diuretics or other sulfonamides derivatives
- case of severe renal impairment (creatinine clearance below 30 ml/min)
- case of severe liver damage
- case of pre-coma associated with liver cirrhosis
- case of Addison's disease
- case of existence of refractory hypokalaemia, hyponatremia or hypercalcaemia
- case of hyperuricaemia
- case of Porphyria
- case of simultaneous application of lithium
- for the use of the medicinal product during the period of pregnancy and breastfeeding see section (application of MONOZID 25 tablets during pregnancy and breastfeeding.)

Be careful with MONOZID 25:

Tell your doctor if you have or have had liver disease. MONOZID 25 is used with caution in patients with reduced hepatic function and in patients with liver disease. If decreased concentration of potassium is present, due to disturbances of the electrolyte balance, it may cause hepatic coma. In the case of the first signs of hepatic coma, it is necessary to discontinue use of the medicine.

It should be used with caution in patients with severe renal impairment, because it reduces the glomerular filtration. In patients with reduced renal function it may lead to accumulation of the medicine, so be sure to tell your doctor if you have or have had kidney disease.

Inform your doctor:

- you have or have had an electrolyte disturbance (reduced concentration of potassium, sodium, magnesium or increased calcium chloride concentration);
- you are being treated from gout or diabetes;
- you have a parathyroid disorder.

For patients who lose potassium and chloride due to vomiting, diarrhea, gastrointestinal drainage, etc. it can affect hypochloremic alkalosis associated with hypokalaemia.

MONOZID 25 can increase the concentration of glucose in the blood and in the urine, so it is necessary to adjust the dose of insulin and oral anti-diabetic.

MONOZID 25 can exacerbate or trigger systemic lupus erythematosus (skin disease and vital organs of autoimmune origin).

MONOZID therapy should be discontinued prior to testing parathyroid function, since it reduces the excretion of calcium, which can lead to incorrect test results.

MONOZID 25 can increase the concentration of cholesterol and triglycerides in the blood, but these effects can be minimized by applying a diet regime.

Warning for use of the medicine in children: the pharmaceutical form is not recommended for children under the age of 5 years.

Taking other medicines with MONOZID 25

Inform your doctor or pharmacist if you are taking or have recently taken to any other medicine, including those that are purchased without prescription, as well as herbal medicines.

Inform your doctor if you are using some of the medicines listed below. A doctor may want to adjust your dose of MONOZID 25 tablets or certain medicines that you use at the same time. These are the following medications:

- medicines for the treatment of high blood pressure (antihypertensives);
- glycosides of Digitalis (for the treatment of diseases of the heart);
- atracurium (muscular relaxant);
- Astemizole, life (in the treatment of allergies);
- sotalol (in the treatment of heart disease);
- corticosteroids (in the therapy of inflammatory processes);
- ACTH (adrenocorticotropic hormone);
- amphotericin B (in the treatment of fungal diseases);
- salbutamol (in the treatment of obstructive lung disease);
- insulin and oral anti-diabetic agents (in the therapy of diabetes);
- non-steroidal anti-inflammatory medicines (in the therapy of inflammatory processes);
- barbiturates (in the therapy of epilepsy);
- Narcotics (pain treatment);
- Lithium (in the therapy of prevention and treatment of mania);
- colestipol and cholestyramine (in the therapy of increased cholesterol in the blood);
- vitamin D, calcium salt;
- Cyclosporine (with organ transplants or the treatment of autoimmune diseases).

Taking the medicine with food or drink

Concomitant use with alcohol can lead to rapid depressurization. Food does not affect absorption of MONOZID 25 tablets.

Pregnancy and breastfeeding

It is necessary to inform the doctor if you are pregnant or think you are pregnant. Your doctor will advise you that you take other medicine instead Monozid 25 tablets, given that the use of Monozid 25 tablets during pregnancy is not recommended. Monozid 25 crosses the placenta and its application after three months of pregnancy may cause potentially harmful effects on the fetus and newborn.

Do not take MONOZID 25 if you are breast-feeding. If the use is necessary, then you should stop breast-feeding.

Driving and using machines

As with other antihypertensive medications, caution is advised when driving or using machines.

Other warnings

MONOZID 25 tablets contain milk sugar (lactose). Therefore, if you are suffering from some form of intolerance to the sugar, inform your doctor before you start using this medicine.

3. HOW TO TAKE MONOZID 25

Take MONOZID 25 exactly as explained by your doctor. If you are not sure, check with your doctor or pharmacist.

High blood pressure (hypertension):

Starting dose is ½ tablets (12.5 mg) to 1 tablet (25 mg) a day. The dose can be gradually increased until it reaches the desired therapeutic effect, or to a common maximum human dose in adults of 2 tablets (50 mg) a day. In severe forms of hypertension it can be combined with other antihypertensive medications, in addition to a single dose of hydrochlorothiazide of ½ tablets (12.5 mg).

When the medicine is used in two daily doses, the first is taken in the morning, just after getting up, and the other one in the early afternoon, as the diuretic effect would not disturb the sleep.

If you are taking MONOZID 25 every day at the same time, it will have the best effect on your blood pressure.

Edema:

The usual dose is 1 tablet (25 mg) up to 4 tablets (100 mg) per day, applied in 1-3 divided doses. In extremely severe cases higher initial dose can be applied (up to a maximum of 8 tablets (200 mg)), but in these cases is recommended the application of a stronger diuretics.

In the case of a good therapeutic response the dose can be reduced to 1 tablet (25 mg) or 2 tablets (50 mg) a day, or even intermittent therapy (every second day, or 3-5 times per week).

Children:

The usual daily dose in children from 6 months to 12 years of age is 1-2 mg/kg body weight, and in children under the age of 6 months is 3 mg/kg. In both cases, the daily dose is divided into two individual doses.

This pharmaceutical form is not recommended for children under the age of 5 years.

Older patients (over 65 years):

Because of the higher incidence of unwanted effects, therapy should be initiated at the lowest recommended dose of ½ tablets (12.5 mg) a day. If necessary, the dose can be increased by half the tablet (12.5 mg).

If you take more MONOZID 25 than you should

If you have taken a higher dose of MONOZID 25 tablets than you should, speak with your doctor or pharmacist!

The most common signs and symptoms of overdose are: drop in blood pressure, loss of electrolytes (reduced concentration of potassium, sodium and chloride), dehydration, lethargy, nausea and weakness. Lethargy can lead to coma in the course of a few hours, with minimal reduction in pulmonary and cardiovascular function and no signs of dehydration and electrolyte disorders.

Therapy of hydrochlorothiazide poisoning is symptomatic: induction of vomiting or lavage of the stomach and induction of active coal; reducing the lowering of pressure and shock and the correction of disorders of water and electrolytes.

A patient with lowered blood pressure should be placed in a recumbent position with the legs raised.

If you forget to take MONOZID 25

If you forget to take a dose, skip the missed dose and take the next dose at the usual time. If you miss two doses or more of them, please consult your doctor.

Never take a double dose (two doses at the same time), to make up for the missed dose.

If you suddenly stop taking MONOZID 25

Do not stop taking this medication without consulting your doctor. If you suddenly stop taking the medicine it can worsen the condition of your disease.

4. POSSIBLE SIDE EFFECTS

As well as other medications 25 MONOZID can cause side effects, although not everybody gets them.

The side effects are mostly mild and reversible.

Disorders of electrolytes and fluids:

reduced concentration of potassium, sodium, magnesium or chloride, or increased concentration of calcium, hypochloremic alkalosis, and increased concentration of uric acid. The first signs of electrolyte disorders are: dry mouth, thirst, weakness, drowsiness, pain or cramps, muscle weakness, drop in blood pressure, decreased the excretion of urine, rapid heartbeat, nausea or vomiting.

If you notice any of these symptoms, inform your doctor about it.

Metabolic and endocrine changes:

pathological changes in the parathyroid gland (increased concentration of calcium and reduced the concentration of phosphate) in the case of prolonged therapy, increased concentration of glucose, the emergence of glucose in the urine, increased concentration of triglycerides and cholesterol in the blood.

Skin and subcutaneous tissue:

photosensitivity, hives and other forms of rashes, itching, Necrotizing Vasculitis, toxic epidermal necrosis (widespread rash with blisters and peeling of the skin on a larger part of the body), cutaneous lupus erythematosus-like reactions, reactivation of Cutaneous Lupus erythematosus.

Gastrointestinal changes:

loss of appetite, anorexia, mild nausea and vomiting, cramps, constipation, diarrhea, inflammation of the pancreas.

Disorders of liver function and bile tract:

jaundice

Vascular Disorders:

drop in blood pressure due to a sudden standing up

Disorders of the nervous system:

dizziness, sensitivity to light, tingling, headache

Psychiatric disorders:

depression, sleep disorder

Disorders of the eye-level:

transient blurred vision, color perception disorder (xantopsia)

Disorders at the level of the kidneys and the urinary system:

Interstitial nephritis

Respiratory, thoracic and mediastinal disorders:

respiratory disorders, including pneumonitis and pulmonary edema

Disorders at the level of the blood and lymphatic system:

depression of bone marrow, anemia (reduction in the number of red blood cells), including aplastic anaemia and hemolytic anemia, a decrease in the number of white blood cells and platelets, dotted the bleeding of the skin (purpura).

Other side effects:

impotence, muscle spasm, serious and life-threatening allergic reactions, weakness, anxiety, fever, inflammation of salivary glands.

If some side effect becomes serious or you notice some side effect that are not specified in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE MONOZID 25

Storage:

Keep out of the reach and sight of children.

Keep at temperature up to 25 C in the original package.

Shelf life:

3 (three) years from the date of manufacture.

Medicine should not be used after the expiry date stated on the carton.

Medicines should not be disposed of via household wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer required. Such behavior will protect our environment.

6. FURTHER INFORMATION

What contains MONOZID 25?

The active substance is: hydrochlorothiazide.

One MONOZID 25 tablets: contains 25 mg of hydrochlorothiazide.

Other substances:

Lactose, maize starch, maize starch (5% mucilage), colloidal anhydrous, magnesium stearate anhydride.

How the tablets 25 MONOZID look like and contents of the pack?

MONOZID 25: whitish, round, tablets with flat surfaces and slanted edges.

MONOZID 25 tablets are packaged in boxes of 30 tablets in blister PVC/Al foil, (1 blister with 30 tablets).

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Farmavita d.o.o. Sarajevo

Igmanska 5a, Vogošća, Sarajevo, Bosnia and Herzegovina.

Manufacturer of the medicinal product

Farmavita d.o.o. Sarajevo (in cooperation with The Jordanian Pharmaceutical Manufacturing, Jordan)

Igmanska 5a, Vogošća, Sarajevo, Bosnia and Herzegovina