

PACKAGE LEAFLET: Information for the patient

TRIAM H

Tablets – (50 mg / 25 mg)

(Triamterene, Hydrochlorothiazide)

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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, or if you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.

In this leaflet:

1. What Triam H is and what it is used for?
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1. WHAT TRIAM H IS AND WHAT IT IS USED FOR?

Triam H is a medicine which promotes water excretion and it is used for its antihypertensive effects.

The active substances of Triam H are triamterene and hydrochlorothiazide.

This medicine is used:

- in high blood pressure (arterial hypertension);
- in cases of abnormal water retention (oedemas) due to cardiac, liver or renal disorders;
- in chronic heart failure.

2. BEFORE YOU TAKE TRIAM H

Do not take this medicine:

- if you are sensitive (allergic) to hydrochlorothiazide, triamterene, other thiazides and also sulphonamides, or to any of the excipients of Triam H;
- if you have severe renal function disorders (creatinine clearance under 30 ml / min.);
- if you have severe impairment of liver function (hepatic precoma / coma);
- if the doctor has noticed that you have high or low blood potassium levels, low sodium levels or high calcium levels;
- if the blood volume is reduced (hypovolemia);
- in anuria or when urine production is highly reduced;
- if you have renal inflammation (glomerulonephritis);
- if you have disease of the adrenal glands causing: weakness, weight loss and a deficiency of hormones in the blood (Addison's disease);
- if you are taking potassium supplements, spironolactone, amiloride, or ACE inhibitors (e.g. enalapril, ramipril, to treat hypertension or cardiac insufficiency);
- in pregnancy;
- during lactation.

Take special care with Triam H:

- if you have mild to moderate renal impairment (creatinine clearance 30 – 60 ml / min.);
- if you have very low blood pressure;
- if you have circulatory blood disorders in brain blood vessels (cerebral sclerosis) or in heart blood vessels (coronary artery disease);
- if you have sugar disease (diabetes mellitus);
- if you suffer from gout or elevated blood uric acid levels;
- if you have liver impairment;
- if you suspect for absence of folic acid (e.g.: in severe liver dysfunctions or in chronic alcoholic abuse);
- if you have 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 Triam H.

Inform your doctor if you think you are pregnant (or you may become pregnant).

Patients with impaired renal function

In patients with renal impairment dosage should be adjusted according to the proper instructions (see section 3 “How to take Triam H?”).

Triam H should not be given to patients with severe renal impairment (creatinine clearance under 30 ml/min.), because its effect may be decreased or even harmful.

To be taken in consideration

Existing or hidden sugar disease, or gout, may get worse if the treatment is prolonged.

In long-term treatment, the blood levels of sugar and uric acid, serum electrolytes (especially potassium, sodium and calcium ions), creatinine, urea and lipids (cholesterol and triglycerides) in serum are recommended to be monitored by the doctor.

During treatment with Triam H you should take considerable amounts of fluids.

Children

There are no data on the efficacy and safety of this drug in children, so no recommendations can be given to this age group.

Elderly

No special measures are necessary.

Effects of misuse as a doping agent

The use of Triam H may cause positive doping results.

The consequences in health caused by the use of Triam H as a doping agent can not be predicted.

Health hazards can not be excluded.

Taking other medicines

Tell your doctor or pharmacist if you are taking / using or have recently taken / used other

medicines, including medicines obtained without a prescription.

The effect of Triam H is affected as follows:

Enhanced effect and possibly enhanced side effects

The antihypertensive effect of Triam H can be enhanced from: diuretics or other antihypertensives, drugs which are used in coronary artery diseases (nitrates), antihypertensives and antiarrhythmic drugs (beta-blockers), vasodilators (wideners of blood vessels), some hypnotics (barbiturates), drugs for treatment of mental diseases (phenothiazines, tricyclic antidepressants) and alcohol.

During concomitant use of Triam H with an ACE-inhibitor (drug which is used in hypertension and heart failure, such as: captopril, enalapril), initially an excessive decrease of blood pressure and also worsening of renal function may occur.

For this reason, treatment with Triam H should be discontinued 2-3 days before beginning treatment with ACE - inhibitors. The dosing of the ACE-inhibitor should be done carefully.

Concomitant use of potassium salts or potassium sparing drugs, like ACE-inhibitors, increases the risk of very high potassium levels in serum.

Taking also drugs which reduce sodium levels, increases the risk, especially in elderly, of the severe absence of this ion.

Decreased effects

Combination of Triam H with some drugs which are used against pain and inflammation (salicylates or nonsteroidal antirheumatics, such as: indomethacin, diclofenac), can decrease the antihypertensive and diuretic effects of Triam H. In patients whose circulating blood volume is decreased because of strong diuretic action of Triam H, concomitant use of nonsteroidal anti-inflammators can cause acute renal failure.

Colestipol and cholestyramine (drugs used to decrease cholesterol levels) reduce the absorption of Triam H.

Triam H affects the effect of the following medicines:

Enhanced effect and possibly enhanced side effects

If Triam H is taken with drugs which cause loss of potassium and magnesium, such as: diuretics which excrete potassium, corticosteroids, ACTH (hormone), laxatives (chronic use), amphotericin B (antifungal drug), carbenoxolone (drug used for the inflammation of oral mucosa), penicillin G (antibiotic) and salicylates (analgesics), the effects and side effects of cardiac glycosides can be enhanced.

When Triam H is taken at the same time with cytostatics (such as: cyclophosphamide, fluorouracil, methotrexate), their myelosuppressive effects can be enhanced.

High doses of salicylates, combined with Triam H, can cause enhanced damage of central nervous system.

When Triam H is used at the same time with muscle relaxant drugs (myorelaxant of curare type), their effect is enhanced and prolonged. In case when Triam H can not be discontinued before taking these drugs, the anesthesiologist should be informed about the treatment with Triam H.

When Triam H is taken at the same time with beta-blockers, there is a high risk of appearance of high sugar levels in the blood.

There is a risk of hypercalcaemia appearance if Triam H is taken with calcium salts and substances containing vitamin D.

Decreased effect

The effect of insulin, oral antidiabetics, drugs which lower uric acid levels and the effect of sympathomimetics (adrenaline, noradrenaline), can be decreased by Triam H.

Other possible interactions

When taken at the same time with methyldopa (antihypertensive), hemolysis (red blood cells damage) have been reported in special cases because of formation of antibodies to hydrochlorothiazide.

When Triam H is taken at the same time with quinidine, the elimination of quinidine is decreased.

Also, Triam H can interact with lithium.

There are other drugs that can interact with Triam H.

Taking Triam H with food and drinks

During treatment with Triam H you should possibly not drink alcohol because it reduces your ability to react.

Pregnancy and lactation

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

Pregnancy

Inform your doctor if you think you are pregnant (or may become pregnant). Your doctor will recommend you to discontinue treatment with Triam H before pregnancy or as soon as possible after you learn for your pregnancy and prescribe another medicine because Triam H can severely harm the fetus.

Lactation

You should not take Triam H during lactation.

Driving and using machines

Treatment with this medicine requires regular medical controls.

The reactions that may appear are individual, and may impair the capacity to react, to drive a car, to operate machines or to work without a secure hold.

This applies more at the beginning of the treatment, when the dose is raised, when the drug is changed and when combined with alcohol.

Important information about some of the excipients of Triam H

This medicinal product contains lactose. Take Triam H only after talking to your doctor if you know that you are intolerant to some sugars.

3. HOW TO TAKE TRIAM H?

Always take Triam H according medical prescription. Check with your doctor or pharmacist if you are not sure.

If not otherwise prescribed by the doctor, the usual dose is:

Hypertension

Initially, take 1 tablet after breakfast and 1 tablet after lunch.

In long-term treatment 1 or ½ tablet in the morning is sufficient.

Oedema

Initially, take 1 or 2 tablets after breakfast and after lunch. Thereafter, the dose is adjusted according to the patient's need.

As maintenance dose, ½ tablet a day or 1 tablet every second day (in the morning), will suffice. According to patient's needs, the dosage can be increased up to 2 tablets a day (1 tablet after breakfast and 1 tablet after lunch).

Heart failure

Dosage adjustment should be made according to patient's physical condition. Regular weight monitoring and the determination of a desired weight play an important role.

1 tablet daily in the morning or 2 tablets daily (after breakfast and after lunch) should be taken.

Dosage for patients with mild to moderate renal impairment

Creatinine clearance [ml/min]	Serum creatinine [mg/100 ml]	Tablets / day (maximum)
100 – 75	up to 1.3	2 x 1
75 – 50	1.3 – 1.5	1 x 1
50 – 30	1.5 – 1.8	1 x ½

Patients with serum creatinine values 1.5 – 1.8 mg/100 ml corresponding to creatinine clearance of 50 – 30 ml/min. should not exceed ½ tablet a day.

Method of administration

Take the tablets whole, with sufficient liquid (preferably a glass of water), after food. Do not take the tablets while in a lying position.

Duration of administration

Treatment with Triam H is usually of a long-term. Your doctor will determine the duration of use. Talk to your doctor or pharmacist if you have the impression that the effect of Triam H is too strong or too weak.

If you take more Triam H than you should

Contact immediately your doctor. He will take the necessary measures.

If you forget to take Triam H

Do not take a double dose if you have missed the previous dose. Continue treatment with the recommended dosages. If you are not sure, talk to your doctor.

If you stop taking Triam H

If you have to stop the treatment or to finish it previously, e.g. because of side effects, talk first with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The frequency of the possible side effects is shown in the table below:

Very common:	more than 1 in 10 patients
Common:	1 to 10 patients among 100
Uncommon:	1 to 10 patients among 1,000
Rare:	1 to 10 patients among 10,000
Very rare:	less than 1 in 10,000 patients
Unknown:	Frequency cannot be estimated from the available data

Triam H is a combination of hydrochlorothiazide and potassium-sparing triamterene. This combination reduces the risk of low blood potassium levels, arrhythmias, raised sensitivity to cardiac glycosides and high levels of potassium and magnesium in blood.

Blood and lymphatic system disorders

Very common: water and electrolyte disorders, which are dose and age related, mainly low levels of potassium, of sodium and chloride and also high levels of calcium in blood. General symptoms appear such as: dry mouth, thirst, tiredness, sleepiness, weakness, dizziness, headache, nervousism, low blood pressure and circulatory disturbances causing excessively low blood pressure upon standing from lying position.

The symptoms of potassium deficiency are: nausea, vomiting, apathy, muscle weakness, constipation until paralytic ileus / intestinal obstruction and changes in ECG. When there is deficiency of magnesium, rarely high levels of magnesium appear in urine, because magnesium is released from the bones.

Uncommon: high levels of potassium in blood, mainly in elderly with renal impairment; blood thickening, with thrombosis and embolism because of increased diuresis and decreased circulatory blood.

Very rare: different forms of anemia (megaloblastic and aplastic anemia), decrease of white blood cells number (leucopenia), excessive decrease in certain white blood cells with the risk of infection and general severe symptoms (agranulocytosis), anemia because of high rates of red blood cells destruction (hemolytic anemia) during concomitant use of methyldopa, decrease of blood platelets (thrombocytopenia).

Immune system disorders

Uncommon: hay fever.

Very rare: anaphylactoid reactions.

Metabolism and nutrition disorders

Very common: increase of blood lipid value (cholesterol and triglycerides) and increase of uric

acid content in blood which can cause gout attacks in sensitive patients.

Raised blood sugar levels and increase of eliminated sugar via urine in healthy patients and in patients with sugar disease (existing or hidden diabetes mellitus) or with potassium deficiency.

Uncommon: acid-base balance metabolic disorders (metabolic acidosis, metabolic alkalosis).

Abusing with diuretics for a long time can cause oedema in the body because of a hormonal disorder (pseudo-Bartter syndrome).

Psychiatric disorders

Uncommon: confusion.

Nervous system disorders

Very common: tiredness, sleepiness, weakness, dizziness, headache, nervosism and apathy because of water and electrolyte disorders.

Eye disorders

Common: mild visual disorders.

Uncommon: lacrimal disorders.

Cardiac disorders

Uncommon: vascular collapse, circulatory disorders causing decrease of blood pressure upon standing from lying down, low blood pressure and changes in ECG because of water and electrolyte disorders.

Vascular disorders

Uncommon: inflammation of blood vessels (vasculitis).

Respiratory, thoracic and mediastinal disorders

Rare: acute inflammation of lung tissue (acute interstitial pneumonia).

Very rare: sudden water accumulation in lungs causing shock. It is thought that this is caused by an allergic reaction to hydrochlorothiazide.

Gastrointestinal tract disorders

Common: increased digestive enzyme levels and pancreas inflammation.

Uncommon: nausea, vomiting, diarrhea, abdominal cramps and pain. Usually, these side effects are avoided when Triam H is taken after food.

Because of low blood potassium levels, intestinal muscle relaxation and constipation, till paralytic ileus and intestinal obstruction may happen.

Hepatobiliary disorders

Common: colecystitis in patients with biliary stones.

Uncommon: jaundice.

Skin and subcutaneous tissue disorders

Uncommon: allergic skin reactions such as: itching, redness, rash, chronic photosensitivity.

Not known: Skin and lip cancer (non-melanomic skin cancer).

Musculoskeletal disorders

Common: muscular tension and skeletal muscle weakness because of low blood potassium levels.

Uncommon: convulsions because of increased diuresis, specific skin reactions (lupus erythematosus).

Renal and urinary tract disorders

Common: increased excretion in urine of substances with nitrogen content and stones production.

Uncommon: acute renal failure because of increased diuresis.

Very rare: worsening of an acute renal failure and also acute or chronic nonbacterial renal inflammation followed by acute renal failure.

After long-treatment with triamterene, very rarely renal stones production is noticed. However, there has been evidence of previous oxalate and urate stones in most of the patients, not related

with triamterene use.

Reproductive organs and breast disorders

Erection disorders may appear when it is combined with beta-blockers, or even during treatment with this drug only.

A blue fluorescence of the urine can be noticed due to the use of Triam H.

If any of the side effects worsens, or if you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. HOW TO STORE TRIAM H?

Keep out of the sight and reach of children.

Do not store in a temperature above 25°C.

Do not use the tablets after the expiry date which is stated on the package.

6. FURTHER INFORMATION

What Triam H contains

The active substances are triamterene and hydrochlorothiazide.

Each tablet Triam H contains 50 mg triamterene and 25 mg hydrochlorothiazide.

The excipients are: lactose monohydrate, microcrystalline cellulose, talc, maize starch, calcium carbonate, sodium croscarmellose, magnesium stearate, povidone and colloidal anhydrous silica.

Content of the pack

Box with 30 tablets.

Marketing Authorization Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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