PACKAGE LEAFLET: Information for the patient

HIDROKLORTIAZID

Tablets – 25 mg

(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 question, ask your doctor or pharmacist.
- This medication 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.

In this leaflet:

1. WHAT HIDROKLORTIAZID IS AND WHAT IT IS USED FOR

Hidroklortiazid, like all thiazide diuretics, increases urinary excretion of sodium and potassium in about equal amounts. As other effects can be mentioned: excretion of potassium and hydrogencarbonate ions, decrease of the excretion of calcium and uric acid retention. In maximum therapeutic doses, all thiazide diuretics are almost equal in concern of diuretic action. The exact mechanism of Hidroklortiazid is still not clear. The site of action of the drug is the peripheral renal tubule and ascendent part of the loop Henle. The drug inhibits the carboanhydrase enzyme thus affecting the transfer of hydrogencarbonates in the kidney. It does not exert any influence on normal arterial pressure. The antihypertensive effect in the initial

stage is related to the reduction of extracellular fluid volume. Several days are needed for the antihypertensive effect. To achieve the optimal therapeutic effect are required 2 - 4 weeks.

Hidroklortiazid tablets are used:

- to treat edema;
- in congestive heart failure, kidney disease, such as nephrotic syndrome;
- in liver cirrhosis;
- to treat hypertension, alone or in combination with other antihypertensive drugs.

Your doctor may have suggested Hidroklortiazid for another reason. Ask your doctor if you want to know why you were given Hidroklortiazid.

2. BEFORE YOU TAKE HIDROKLORTIAZID

Do not take Hidroklortiazid:

- if you are allergic to hydrochlorothiazide or to any other diuretics, sulfamidic derivatives;
- if you are allergic to any of the excipients of Hidroklortiazid listed in section 6;
- if you suffer from anuria;
- if you suffer from renal failure;
- if you suffer from severe hepatic failure;
- if you suffer from hypokalemia, hyponatraemia, hypercalcaemia and hyperuricaemia;
- to treat hypertension during pregnancy.

If you think you have any of the conditions mentioned above, do not take the pills, talk to your doctor first and follow the given advices.

Take special care when taking Hidroklortiazid

Patients who are being treated with Hidroklortiazid or other thiazide diuretics, in general must receive an adequate amount of potassium, by taking a rich potassium diet (dried fruits, potatoes, tomatoes) or medication (potassium chloride).

Tell your doctor if:

- you suffer from kidney or liver disease;
- you suffer from severe congestive heart failure, and you have edema, because in these cases hyponatremia may occur, especially when using high doses and salt is limited;
- you have signs of diabetes (fatigue, thirst, dizziness, etc.) during treatment with Hidroklortiazid since latent diabetes may not be anymore latent during treatment with thiazide diuretics;
- you are diabetics who use insulin, in this case blood glucose concentrations must be kept under control, because insulin needs may change during treatment with Hidroklortiazid;
- you have hyperuricemia which may cause gout attacks (in patients with gout, uric acid concentrations in serum should be measured carefully in regular intervals);
- you suffer from heart disease or other illnesses; Hidroklortiazid use should be avoided if safer alternatives exist;
- 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 Hidroklortiazid;
- you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking Hidroklortiazid. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Taking other medicines

Different drugs may be affected by Hidroklortiazid or may affect the way it acts, so during their concomitant use may be necessary to decrease or increase the amount of Hidroklortiazid. Your doctor or pharmacist will advise you.

Tell your doctor if you are taking any other medicines, including medicines obtained without a prescription.

Hidroklortiazid and other thiazide diuretics may affect the effect of all these drugs: allopurinol, anesthetics, anticoagulants, antigout agents, antineoplastics, calcium salts, digitalic glycosides,

insulins, lithium, loop diuretics, methyldopa, non-depolarizing myorelaxants, vitamin D.
Drugs that affect the effect of Hidroklortiazid and other diuretics are: amphotericin B, anticholinergics, corticosteroids, methenamine (hexamethylene-tetramine) and non-steroidal anti-inflammatory drugs.

Pregnancy
Tell your doctor or pharmacist if you are pregnant or are planning to become pregnant.
Hidroklortiazid and all thiazide diuretics should not be used for treatment of hypertonia during pregnancy.

Breastfeeding
Tell your doctor or pharmacist if you are breast-feeding. The drug is excreted into breast milk and may inhibit lactation, therefore it should be avoided during breastfeeding.

Important information about some of the excipients of Hidroklortiazid
This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE HIDROKLORTIAZID
Always take Hidroklortiazid as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you feel that Hidroklortiazid effects are too strong or too weak, talk to your doctor or pharmacist.
The dose for tablets is as follows:
Adults
Edema: The initial dose is 25 mg to 50 mg per day for several days, while the maintenance dose is 25 mg to 100 mg per day or every other day; resistant patients may use up to 200 mg per day.

Hypertension: The initial dose is 50 mg per day, as a single dose or in 2 divided doses. Higher doses than 50 mg often are associated with significant reductions of potassium in serum. For the patients who use other antihypertensives at the same time, usually, higher doses than 50 mg are not needed.

Your doctor may ask you to take Hidroklortiazid for a longer time. Ask your doctor for advice if you are not sure for how long you should take it.
Hidroklortiazid tablets should be swallowed with a full glass of water.

If you take more Hidroklortiazid

If you take more Hidroklortiazid than you should, or if the children have accidentally taken this drug, please contact your doctor, hospital or call the emergency to get an opinion on the risk and advice on the actions that should be taken.

If you forget to take Hidroklortiazid

If you forget a dose (or more doses), take the next dose when it is the usual time to take it.
Do not take a double dose (or higher doses) to make up for a forgotten dose (doses)!
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines can cause side effects. Sometimes they are serious, but most of the times they are not. Do not panic by this list of possible side effects. You may not get any of them.

Tell your doctor if any of the following side effects bothers you:

- gastrointestinal disorders (anorexia, gastric irritation, nausea, vomiting, abdominal pain, flatulence, diarrhoea, constipation, pancreatitis, sialadenitis, dry mouth);
- central nervous system disorders (dizziness, headache, paresthesia, weakness, sleeplessness, fatigue);
- haematological disorders (leukopenia, thrombocytopenia, agranulocytosis, aplastic or hyperplastic anemia, hemolytic anemia, megaloblastic anemia);
- orthostatic hypotension;
- impotence, libido reduction;
- interstitial nephritis, azotemia, increased urea nitrogen and creatinine in blood;
- jaundice, liver enzyme disorders;
- hyperglycemia, glucosuria, hyperuricemia, hypokalemia, hypochloremia, hyponatremia;
- blurred vision, xanthopsia, muscle cramps or spasms, fever and anaphylactic reactions;

- skin and lip cancer (non-melanoma skin cancer) (unknown frequency);
- decrease in 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 angle-closure glaucoma).

When side effects are reversible, the treatment is not discontinued. When these effects are moderate or severe, the dose of Hidroklortiazid should be reduced or the treatment should be stopped.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE HIDROKLORTIAZID

Keep this medicine out of the sight and reach of children.
Do not use Hidroklortiazid after the expiry date which is stated on the package.
Do not store above 25°C!

6. FURTHER INFORMATION

What Hidroklortiazid 25 mg tablets contain

The active substance is hydrochlorothiazide.
Each tablet contains 25 mg hydrochlorothiazide.
The excipients are: lactose, microcrystalline cellulose, magnesium stearate and talc.

Contents of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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