

PACKAGE LEAFLET: INFORMATION FOR THE USER

HYGROTON

25 mg tablets

CHLORTALIDONE

• 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?

1. What Hygroton is and what it is used for
2. Before you take Hygroton
3. How to take Hygroton
4. Possible side effects
5. How to store Hygroton
6. Further information

1. WHAT HYGROTON IS AND WHAT IT IS USED FOR

HYGROTON is a diuretic which helps to reduce the amount of water in the body. It is used to treat high blood pressure and heart failure and to reduce fluid retention, which occurs in some diseases of the kidney and the liver. Also, it is used in the condition called diabetes insipidus.

2. BEFORE YOU TAKE HYGROTON

If some of the answers to the following questions are YES, tell your doctor.

- Have you ever had a rash or perhaps any other allergic reaction while you are taking diuretics or sulfonamides or have you had an allergic reaction to any component of the tablet HYGROTON?
- Are you taking any other medicines (purchased or obtained on prescription)? Some medicines can affect the action of this medicine, and therefore check with your doctor or pharmacist before taking any other medicines, especially:
 - any other medicine to treat blood pressure or heart problems (e.g. digoxin);
 - any medicine for muscle relaxation during anesthesia;
 - medicines for the treatment of diabetes;

- corticosteroids;
 - NSAIDs against the painful conditions, e.g. indomethacin;
 - amphotericin (against infections);
 - lithium pills (for mental illness);
 - carbenoxolone (against ulcers);
 - vitamin D or calcium salts (as replacement therapy);
 - medicines for the treatment of cancer (such as cyclophosphamide or methotrexate);
 - anticholinergics, e.g. atropine, (when difficulties with the stomach and intestines);
 - amantadine (against Parkinson's disease and viral infections);
 - cholestyramine (against elevated levels of lipids in the blood);
 - Cyclosporine (transplantation, rheumatic diseases and difficulties with the skin);
 - allopurinol (against gout);
 - salbutamol or some medicine, okay (against asthma and premature labors) and ritodrine.
- are you pregnant or planning to become pregnant, or breast-feeding?
 - Do you as pregnant women have high blood pressure?
 - Do you have serious problems with your kidneys or liver?
 - Do you suffer from gout?
 - Do you have Addison's disease?
 - Have you been told that you have low levels of potassium or sodium in the blood?
 - Do you have any serious disorder of the blood vessels?
 - Do you have diabetes?
 - Are you taking any medication for high cholesterol?
 - Have you been told that you have elevated levels of calcium in the blood?

Other special warnings

- Your doctor will probably perform laboratory tests from time to time. It is common and therefore you don't need to worry.
- Since those tablets can reduce the amount of salt in the body, you have to avoid very strict diet with reduced salt content.

Pregnancy and breastfeeding

Hygroton is not recommended during pregnancy and breastfeeding.

The medicine is excreted into breast milk, and high doses can reduce the formation of milk.

Driving and using machines

There are no data on the impact on the ability to drive and use machines. If you feel dizzy after you start taking the medicine, do not operate a motor vehicle or operate machinery while these effects persist.

3. HOW TO TAKE HYGROTON

It is important to take the tablets at a specific time. Take them according to doctor's instructions. Carefully read the instructions, so that you know when to take them. The doctor will determine the appropriate starting dose based on your situation and will monitor your progress. If necessary, the dose may be increased or decreased. HYGROTON is best taken in the morning with food. Swallow the tablets whole, with some water.

Usual doses are as follows:

High blood pressure: 25 to 50 mg a day.

Heart failure: 25 to 200 mg a day.

Fluid retention associated with kidney or liver disease: up to 50 mg a day.

Diabetes insipidus: 100 mg twice a day. The dose can be reduced to 50 mg a day.

Children

A suitable dosage will be determined by your doctor based on the age and weight of your child.
The usual dose is 2 mg/kg/day,

Older patients, and those who have difficulties with kidney problems, may be given a lower dose.

If you are not sure how many tablets to take, ask your doctor or pharmacist. Do not stop taking the tablets at once. First, you should consult with your doctor.

What to do if you take more medicine than you should

If by mistake you take too many tablets, contact your doctor or nearest hospital casualty department. Show the remaining medicine or empty packaging to the doctor.

What to do if you miss a dose

If you forget to take a dose, take it as soon as possible, unless it is already close to the time for taking the next dose. DO NOT TAKE a double dose. Then continue according to the regular schedule.

4. POSSIBLE SIDE EFFECTS

As well as other medicines, HYGROTON can cause side effects.

The following side effects may occur during use of HERPLEX CREAM:

Very common- reduced quantity of potassium, hyperuricaemia and increase in blood lipid,

Common: dizziness, impotence in men, the feeling of fainting when standing up, reduced appetite, urticaria and other forms of rashes, reduced amount of sodium, reduced amount of magnesium, reduced level of sugar in the blood.

Rare: hypercalcaemia, tingling in the fingers and toes (tingling and numbness), headache, nausea, vomiting, stomach pain, diarrhea or constipation, blockage of bile in the liver, jaundice, cardiac arrhythmias, pulmonary edema, thrombocytopenia, Leucopenia, agranulocytosis, Eosinophilia, photosensitivity, glucosuria and nephritis.

Very rare: pancreatitis, alkalosis.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE HYGROTON

Keep at a temperature up to 25°C.

Keep it in a safe place out of reach of children.

Shelf life is five years and is printed on the packaging. Do not use the tablets after expiration date.

6. FURTHER INFORMATION

What do HYGROTON TABLETS contain?

The active ingredient in the HYGROTON tablets is chlortalidone. Each tablet contains 25 mg of chlortalidone. The HYGROTON TABLETS also contain the following excipients: lactose monohydrate, corn starch, silicon dioxide, colloidal anhydrous, magnesium stearate, talc, iron oxide yellow (E172) and iron oxide red (E172).

What do HYGROTON TABLETS look like and contents of the Pack?

HYGROTON TABLETS are round, bright orange, biconvex tablets, on one side marked with the inscription PLIVA and on the other with a parting line.

HYGROTON TABLETS are available in a pack of 20 tablets in blister (2 blisters of 10 tablets), in a box.

Regime of dispensing

The medicine is issued on doctor`s prescription.

Manufacturer

PLIVA Hrvatska d.o.o.
Prilaz baruna Filipovića 25,
Zagreb, Croatia

Manufacturer of the medicinal product

PLIVA Hrvatska d.o.o. (in collaboration with NOVARTIS Pharma AG, Basel, Switzerland)
Prilaz baruna Filipovića 25,
Zagreb, Croatia