

# Hygroton

## Chlorthalidone 25 mg tablets

### What is in this leaflet

Please read this leaflet carefully before you start taking Hygroton. This leaflet answers some common questions about Hygroton.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Hygroton against the benefits they expect it will have for you.

**If you have any concerns about this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.**

You may need to read it again.

### What Hygroton is used for

**Hygroton is used to treat high blood pressure, also called hypertension.**

Everyone has blood pressure. This pressure helps to move your blood around your body. Your blood pressure may be different at various times of the day, depending on how busy you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have it is to have your blood pressure checked on a regular basis. You may feel fine and have no symptoms but, if high blood pressure is not treated, it can lead to serious health problems. Hygroton helps to lower your blood pressure.

**Hygroton is also used to treat fluid buildup caused by heart, liver or kidney problems.**

Hygroton belongs to a group of medicines called diuretics (commonly called fluid or water pills). These medicines help to reduce the amount of salt and water in the body by acting on the kidneys to increase the flow of urine.

Hygroton is also used to treat fluid retention in premenstrual syndrome, only if the gain in weight is the main problem reported.

It can be used alone or in combination with other medicines to treat your condition.

Hygroton is also used to:

- Treat heart failure
- Prevent the formation of kidney stones in patients with increased levels of calcium in the urine

Ask your doctor if you have any questions about why Hygroton has been prescribed for you.

Your doctor may have prescribed Hygroton for another reason. Hygroton is only available with a doctor's prescription. It is not addictive.

## **Before you take Hygroton**

### **When you must not take it**

**Do not take Hygroton if you have an allergy to:**

- **chlorthalidone (the active ingredient) or any of the other ingredients of Hygroton listed at the end of this leaflet**
- **any other medicines with a similar structure e.g. thiazide diuretics, sulpha drugs**

**If you are allergic to other medicines and you are not sure if they have a similar structure to Hygroton, ask your doctor or pharmacist.**

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take Hygroton if you have any of the following health problems/medical conditions:**

- **severe kidney or liver failure**
- **too little potassium or sodium in your blood**
- **too much calcium in your blood**
- **gout (or you have had gout in the past)**
- **high blood pressure during pregnancy**

If you are not sure whether any of the above medical conditions apply to you, your doctor can advise you.

**Do not take Hygroton after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

In that case, return it to your pharmacist.

### **Before you start to take Hygroton**

**Tell your doctor if you have any of the following medical conditions:**

- **milder forms of kidney or liver trouble**
- **a problem with your heart or blood circulation**
- **diabetes**
- **high cholesterol**

If 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 weeks of taking Hygroton. 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.

**Tell your doctor if you are elderly.**

Your doctor may want to take special precautions if you have any of the above conditions.

**Tell your doctor if you are pregnant or intend to become pregnant.**

**Hygroton may affect your baby during pregnancy and at birth. Your doctor can discuss the risks and benefits of taking this medicine during pregnancy.**

**Tell your doctor if you are breast-feeding or intend to breast-feed.**

**The active ingredient in Hygroton passes into breast milk and there is a possibility that your baby could be affected.**

**Tell your doctor if you are lactose intolerant.**

This medicine contains lactose.

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

Your doctor will want to know if you are prone to allergies.

### **Taking other medicines**

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Hygroton.**

Other medicines and Hygroton may interfere with each other. These include:

- some medicines used to treat high blood pressure or heart problems e.g. digoxin, ACE inhibitors (e.g. lisinopril), guanethidine, methyldopa,  $\beta$ -blockers (e.g. propranolol hydrochloride), vasodilators (e.g. bosentan), calcium antagonists (e.g. amlodipine), ketanserin
- medicines for diabetes, e.g. insulin, metformin
- medicines for arthritis, pain or inflammation such as non-steroidal anti-inflammatory drugs (called NSAIDs), e.g. indomethacin
- steroid medicines for allergy and inflammation, such as cortisone or prednisone
- lithium, a medicine used for some mental conditions
- cholestyramine, a medicine used to lower high cholesterol
- allopurinol, a medicine for gout
- vitamin D or calcium supplements, used for replacement therapy
- cyclosporine, a medicine used to suppress the immune system
- amantadine, a medicine for Parkinson's disease
- anticholinergic medicines, used for relieving stomach cramps or spasms, preventing travel sickness and treating Parkinson's disease, e.g. atropine, biperiden
- cytotoxic medicines used for treatment cancer, e.g. cyclophosphamide, methotrexate
- curare derivatives and  $\beta_2$ -agonists (e.g. epinephrine), used for relaxing muscles

- diazoxide, a medicine used for treatment of low blood sugar
- adrenocorticotrophic hormone (ACTH), used for treatment of infantile spasms
- amphotericin, a medicine used for treatment of fungal infections
- carbenoxolone, a medicine used for treatment of ulcers
- oral anticoagulants, medicines used for preventing clotting of blood, e.g. warfarin
- digitalis, a medicine used to treat heart failure and irregular heart beat

You may need to take different amounts of your medicines or to take different medicines while you are taking Hygroton. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking Hygroton.

## **How to use Hygroton**

**Follow the directions given to you by your doctor and pharmacist carefully.**

These directions may differ from the information contained in this leaflet.

**If you do not understand the instructions on the label, ask your doctor or pharmacist for help.**

### ***How much to take***

You will usually be started on a low dose of Hygroton and, if necessary, your doctor will increase the dose gradually.

For an adult, the usual dose ranges from 12.5 mg to 50 mg, taken each day or sometimes every other day. For a child, the dose needed will depend on how much the child weighs.

### ***How to take it***

**Take the tablets during a meal with a full glass of water.**

**If you take only one dose of Hygroton each day, take it in the morning unless your doctor tells you otherwise.**

**If you take more than one dose each day, take the last dose no later than 6 PM if possible.**

Diuretic medicines tend to increase the amount of urine you pass. It is best to take the last dose of medicine no later than 6 p.m. so that you will not have to get up during the night to urinate.

### ***How long to take it***

**Continue taking Hygroton for as long as your doctor tells you to.**

This medicine helps to control your symptoms but it does not cure your condition. Your doctor will check your progress to make sure the medicine is working and will discuss

with you how long your treatment should continue.

### ***If you forget to take it***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take the dose as soon as you remember, and then go back to taking it as you would normally.**

**Do not take a double dose to make up for the one that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.**

## **While you are taking Hygroton**

### ***Things you must do***

**Be sure to keep all of your doctor's appointments so that your progress can be checked.**

Your doctor will want to check your heart and blood pressure and do regular blood tests to make sure the treatment is working and to prevent unwanted side effects.

**Follow any instructions that your doctor gives you to maintain the correct level of a salt called potassium in your blood.**

Hygroton may sometimes cause your body to lose too much potassium. To help prevent this from happening, your doctor may ask you to:

- have foods that have a high potassium content such as orange juice or other citrus fruit juices
- take a potassium supplement
- take another medicine to help prevent the loss of potassium

It is important not to add potassium to your diet without your doctor's advice. Extra potassium may not be needed and, in some cases, could be harmful.

**If you become sick and have severe or continuing vomiting or diarrhoea, tell your doctor.**

Vomiting and diarrhoea may cause your body to lose too much salt and water, causing unwanted side effects.

**If you become pregnant while taking Hygroton, tell your doctor.**

Your doctor can discuss with you the risks and benefits of taking it while you are

pregnant.

**If you are being treated for diabetes, monitor your blood sugar carefully and report any problems to your doctor.**

Hygroton may increase your blood sugar levels and affect how well your diabetes is controlled. The dose of your medicines for diabetes may have to be changed.

**If you are going to have surgery, tell your doctor or dentist that you are taking Hygroton.**

This will help to prevent unwanted side effects such as a sudden drop in blood pressure.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Hygroton.**

**Tell any other doctor, dentist or pharmacist who treats you that you are taking Hygroton.**

### ***Things you must not do***

**Do not give this medicine to anyone else, even if their condition seems similar to yours**

**Do not take it to treat any other complaints unless your doctor tells you to.**

### ***Things to be careful of***

**Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Hygroton until you know how it affects you.**

This medicine may cause dizziness, light-headedness or blurred vision in some people. If you have any of these symptoms, do not drive or do anything else that could be dangerous.

**If this medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.**

These symptoms may be due to a sudden fall in your blood pressure. If this problem doesn't go away, talk to your doctor. To avoid symptoms of low blood pressure, here are some hints that may help:

- Stand up slowly to help your body get used to the change in position and blood pressure
- If you feel dizzy, sit or lie down until you feel better

- If you feel faint, breathe deeply and bend forward with your head between your knees
- Take extra care when exercising, driving or standing for long periods, especially in hot weather. Drink plenty of fluids, especially if you sweat a lot.
- Avoid alcohol or medicines to help you sleep as they may make your blood pressure fall even more.

**Be careful to stay out of direct sunlight as much as possible until you find out if your skin is more sensitive to the sun than usual. Wear protective clothing and use a sunscreen. Do not use a sunlamp.**

In rare cases, this medicine can make the skin more sensitive to sunlight than usual.

## **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Hygroton.**

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age, you may have an increased chance of getting side effects.

**Do not be alarmed by these lists of possible side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following side effects and they worry you:**

- dizziness or light-headedness, especially on standing up or when getting up from a sitting or lying position
- loss of appetite, stomach upset, nausea (feeling sick) or vomiting
- diarrhoea or constipation
- headache
- blurred vision
- 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)
- problems with sexual function

**Tell your doctor immediately if you notice any of the following:**

- signs of allergy such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- unusual tiredness, lack of energy or weakness, sometimes with nausea and a feeling of disorientation
- symptoms caused by lack of white blood cells, such as constant “flu-like” symptoms (chills, fever, sore throat, aching joints, swollen glands)
- symptoms caused by low blood platelet count, such as unusual bleeding or bruising; reddish or purplish blotches under the skin
- pain in the abdomen with nausea, vomiting and fever
- yellowing of the skin and/or eyes
- irregular heart beat
- coldness, burning, tingling or numbness or pain in arms and legs
- symptoms caused by high uric acid levels in the blood, which may cause gout such as pain and swelling of the joints, often in the big toe
- difficulty urinating, sometimes with pain or fever
- symptoms of sunburn (redness, itching, swelling, blistering) that happen much more quickly than normal
- symptoms caused by an increase in some white blood cells, such as fever, cough, swollen lymph nodes, itching, diarrhoea
- symptoms caused by low blood levels of potassium, such as muscle weakness, muscle twitching or abnormal heartbeat
- symptoms caused by increased levels of cholesterol in the blood, such as chest pain, nausea, extreme fatigue, numbness or coldness in your extremities
- symptoms caused by low levels of sodium in the blood, such as tiredness, confusion, muscle twitching, fits or coma
- symptoms caused by low levels of magnesium in the blood, such as abnormal eye movements, convulsions, fatigue, muscle weakness
- symptoms caused by high blood sugar levels, such as tiredness, weakness or feeling thirsty
- symptoms caused by high levels of calcium in the blood, such as agitation, sore eyes, abdominal pain
- worsening of symptoms of diabetes, like passing large amounts of urine and constantly feeling thirsty
- symptoms caused by low levels of chloride in the blood, such as dry mouth, thirst, gastrointestinal disturbances (including nausea, vomiting), weakness, lethargy, drowsiness, restlessness, seizures, confusion, headache, muscle

pains or cramps, hypotension

- symptoms of inflammation of blood vessels such as fever, weight loss, muscle pain, nose bleeds
- symptoms of fluid build-up in the lungs, such as breathlessness, which may be very severe and usually worsens on lying down
- symptoms of inflammation of the pancreas, such as severe upper stomach pain, often with nausea and vomiting
- sugar (glucose) or blood in the urine (this would show up when your doctor or nurse tests your urine)

Hygroton may interfere with the results of diagnostic tests like the bentiromide test.

**Tell your doctor if you notice anything else that is making you feel unwell.**

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects e.g. raised cholesterol levels, can only be found when laboratory tests are done.

## **Overdose**

**Immediately telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre, Dunedin (telephone 0800 POISON OR 0800 764 766) for advice, or go to the Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much Hygroton. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.**

Some of the symptoms of an overdose may include nausea (feeling sick), dizziness, sleepiness, muscle spasms, low blood pressure and irregular heart beat.

## **After taking Hygroton**

### **Storage**

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place below 30°C.
- Do not store Hygroton or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

**Keep this medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## ***Disposal***

**If your doctor tells you to stop taking Hygroton or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## **Product description**

Hygroton 25 mg tablets are speckled pale orange, round, approximately 7.1 mm diameter, flat tablets with bevelled edges. The tablets are imprinted CW and a score line on one side and nothing on the other side. Each tablet contains 25 mg of chlorthalidone. Bottles of 50 tablets.

## ***Other ingredients***

*Hygroton tablets also contain:*

- colloidal anhydrous silica
- lactose
- magnesium stearate
- maize starch
- purified talc
- iron oxide yellow (E172) iron oxide red (E172)

Hygroton does not contain sucrose, gluten, tartrazine or any other azo dyes.

## ***If you want to know more***

Talk to your doctor or pharmacist. They will be able to answer any questions you may have.

## **Distributor**

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