

Hylaton

12.5mg, 25mg & 50mg Tablets

Chlortalidone

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hylaton Tablets are and what they are used for
2. What you need to know before you take Hylaton Tablets
3. How to take Hylaton Tablets
4. Possible side effects
5. How to store Hylaton Tablets
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1. What Hylaton Tablets are and what they are used for

Hylaton Tablets belong to a group of medicines called thiazide diuretics.

Thiazide diuretics help to reduce the amount of water in your body. They do this by increasing the amount of water that you pass as urine. They are sometimes called 'water tablets'.

Hylaton Tablets are used to:

- treat high blood pressure (hypertension)
- treat heart failure
- help reduce the fluid retention that occurs with some kidney or liver diseases
- treat diabetes insipidus (a condition in which an individual produces large amounts of dilute urine and is constantly thirsty).

2. What you need to know before you take Hylaton Tablets

Do not take Hylaton Tablets:

- if you are allergic to Hylaton or sulphonamides such as sulfamethoxazole or any of the other ingredients of this medicine (see Section 6. Contents of the pack and other information)
- if you are not passing any urine at all
- if you have severe kidney or liver problems
- if you have low blood levels of potassium which can cause muscle weakness, muscle twitching or abnormal heartbeat
- if you have low blood levels of sodium which can cause tiredness, confusion, muscle twitching, fits or coma
- if you have high blood levels of calcium which can cause loss of appetite, tiredness or muscle weakness
- if you have ever had gout or kidney stones
- if you have Addison's disease (which is a condition where your adrenal gland is not producing enough steroids)
- if you are taking lithium.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Hylaton Tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Hylaton Tablets:

- if you suffer from any other liver or kidney problems;
- if you are on a low-salt diet;
- if you suffer from diabetes mellitus (increased levels of sugar in the blood);
- if you have high cholesterol levels;
- if you have recently had an anaesthetic;
- if you are elderly.
- 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 a week of taking Hylaton Tablets. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Hylaton Tablets.

Other medicines and Hylaton Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This applies to medicinal products subject to medical prescription or those obtained without prescription, especially:

- other treatments for high blood pressure or heart problems such as:
 - ACE inhibitors (for example, lisinopril)
 - beta blockers (for example propranolol hydrochloride)
 - methyl dopa
 - vasodilators (for example bosentan)
 - calcium channel blockers (for example amlodipine)
 - guanethidine
- corticosteroids such as prednisolone or betamethasone - used to treat allergic and inflammatory diseases and immune reactions
- adrenocorticotrophic hormone (ACTH) - used to treat a number of different conditions, including ulcerative colitis (a form of inflammatory bowel disease), Crohn's disease (a form of chronic inflammatory bowel disease) and rheumatoid arthritis

- corticosteroids such as prednisolone or betamethasone - used to treat allergic and inflammatory diseases and immune reactions
- cytotoxic agents such as cyclophosphamide or methotrexate - used to treat cancer
- asthma treatments such as salbutamol or formoterol
- amphotericin - used to treat infections
- carbenoxolone - used to treat ulcers
- insulin and other treatments for diabetes such as chlorpropamide or glibenclamide
- digoxin – for an irregular heartbeat
- lithium - used to treat mental illness
- anticholinergics such as atropine sulphate or hyoscine (butylbromide) - for abdominal or stomach spasms or cramps
- colestyramine - used to reduce cholesterol levels and prevent heart disease
- amantadine - used to treat Parkinson's disease or viral infections
- allopurinol - used to treat gout (a complex type of arthritis)
- non-steroidal anti-inflammatories (NSAIDs) such as aspirin or indometacin - used for pain relief or rheumatism
- ciclosporin - used to treat rheumatic disease or skin complaints or after a transplant
- calcium salts or vitamin D - used for replacement therapy.

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

Hylaton Tablets with food, drink and alcohol

It is best to take Hylaton Tablets in the morning with food. Swallow your tablets whole with a drink of water.

You should avoid low salt diets. Taking Hylaton Tablets may reduce the amount of salt in your body.

If you are on a low salt diet check with your doctor first before taking Hylaton Tablets.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Hylaton Tablets if you are pregnant or trying to become pregnant. Tell your doctor, immediately, if you become pregnant during treatment with Hylaton Tablets.

Breast-feeding

Do not take Hylaton Tablets if you are breast-feeding because the active substance of Hylaton Tablets passes into breast milk and could harm your baby.

Driving and using machines

Hylaton Tablets may cause dizziness. If you feel dizzy when you start taking these tablets, do not drive or work with machinery until these effects have worn off.

Hylaton Tablets contains lactose

Hylaton Tablets contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Important information about Hylaton Tablets

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Hylaton Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will choose a suitable starting dose for your particular condition and monitor your progress. If necessary, this dose can be increased or reduced.

Whilst you are taking Hylaton Tablets, your doctor may want to carry out a number of tests from time to time. This is quite usual and nothing to worry about.

It is best to take Hylaton Tablets in the morning with food. Swallow your tablets whole with a drink of water.

Adults

The usual doses for adults are as follows:

- High blood pressure:
 - The starting dose is 25 mg (half a tablet) a day. Your doctor may increase this to 50 mg (one tablet) a day if necessary.
- Heart failure:
 - The starting dose is 25 mg (half a tablet) a day. Your doctor may increase this up to 200 mg (four tablets) a day if necessary.
- Fluid retention associated with kidney or liver disease:
 - Up to 50 mg (one tablet) a day.
- Diabetes insipidus (a disease in which an individual produces large amounts of dilute urine and is constantly thirsty):
 - The starting dose is 100 mg (two tablets) twice a day. Your doctor may reduce your dose to 50 mg (one tablet) a day.



Children

Your doctor will choose a suitable dose based on your child's age and weight.

Elderly patients or those with kidney problems

Your doctor may give you a lower dose because your body may not get rid of Hylaton Tablets as quickly as normal.

If you are not sure how many tablets to take, ask your doctor or pharmacist. Do not stop taking your tablets suddenly. Ask your doctor first.

If you take more Hylaton Tablets than you should

If you accidentally take more Hylaton Tablets than you should tell your doctor immediately or contact your nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

If you forget to take Hylaton Tablets

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then go on as before.

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

4. Possible side effects

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

If you get any of the following effects tell your doctor or pharmacist immediately:

Very common (may affect more than 1 in 10 people):

- low blood levels of potassium which can cause muscle weakness, muscle twitching or abnormal heartbeat
- increased blood levels of uric acid
- increased blood levels of cholesterol.

Common (may affect up to 1 in 10 people):

- low levels of sodium which can cause tiredness, confusion, muscle twitching, fits or coma
- low levels of magnesium
- high blood sugar levels which can cause tiredness, weakness or feeling thirsty
- nettle rash
- skin rash
- low blood pressure which may make you feel dizzy when you stand up
- dizziness
- loss of appetite
- upset stomach
- impotence in men.

Rare (may affect up to 1 in 1,000 people):

- increased calcium in the blood which can cause agitation, sore eyes, abdominal pain
- sugar in the urine (this would show up when your doctor or nurse tests your urine)
- worsening of diabetes
- yellowing of the skin or eyes caused by liver or blood problems (jaundice)
- increased sensitivity of your skin to sunlight
- abnormal heartbeat the symptoms of which include palpitations and fainting
- pins and needles
- headache
- feeling or being sick
- stomach pain
- constipation
- diarrhoea
- reduction in blood platelets which increases the risk of bruising or bleeding
- severe reduction in the number of white blood cells which makes infection more likely
- an abnormally high amount of eosinophils (type of white blood cell) in the blood
- breathing problems
- problems with your kidneys.

Uncommon side effects (may affect up to 1 in 100 people)

- gout which causes pain and swelling in the joints.

Very rare (may affect up to 1 in 10,000 people):

- low levels of chloride in the blood, symptoms include dry mouth, thirst, gastrointestinal disturbances (including nausea, vomiting), weakness, lethargy, drowsiness, restlessness, seizures, confusion, headache, muscle pains or cramps, hypotension
- inflammation of the pancreas which causes severe stomach and back pain.

Frequency unknown:

- 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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hylaton Tablets

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or container after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hylaton Tablets contain

- The active substance is chlortalidone:
Each 12.5mg Hylaton Tablet contains 12.5 mg of chlortalidone.
Each 25mg Hylaton Tablet contains 25 mg of chlortalidone.
Each 50mg Hylaton Tablet contains 50 mg of chlortalidone.
- The other ingredients are
- 12.5mg tablets - cellulose microcrystalline, lactose, monohydrate, povidone, sodium starch glycolate (Type A) and magnesium stearate.
- 25mg tablets - cellulose microcrystalline, lactose, monohydrate, povidone, sodium starch glycolate (Type A), yellow iron oxide (E172), red iron oxide (E172) and magnesium stearate.
- 50mg tablets - cellulose microcrystalline, lactose, monohydrate, povidone, sodium starch glycolate (Type A), yellow iron oxide (E172) and magnesium stearate.

What Hylaton Tablets look like and contents of the pack

Hylaton 12.5mg Tablets are white, circular and convex tablets without break line, with a diameter of $5.0 \pm 0.2\text{mm}$.

Hylaton 25mg Tablets are pale pink to reddish, circular and convex tablets without break line, with a diameter of $7.0 \pm 0.2\text{mm}$.

Hylaton 50mg Tablets are yellow, circular and convex tablets without break line, with a diameter of $9.0 \pm 0.2\text{mm}$.

Hylaton Tablets are supplied in blister packs of 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This leaflet was last revised in September 2020.

M0351LAMUKNAB1-P1-001

