

Package leaflet: Information for the user

Kaliumlosartan HCTZ axcount 50/12,5 mg, filmomhulde tabletten Kaliumlosartan HCTZ axcount 100/25 mg, filmomhulde tabletten losartan potassium and hydrochlorothiazide

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 Kaliumlosartan HCTZ axcount is and what it is used for
2. What you need to know before you take Kaliumlosartan HCTZ axcount
3. How to take Kaliumlosartan HCTZ axcount
4. Possible side effects
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1. What Kaliumlosartan HCTZ axcount is and what it is used for

Kaliumlosartan HCTZ axcount is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Angiotensin II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin II to these receptors, causing the blood vessels to relax which in turn lowers in the blood pressure. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

Kaliumlosartan HCTZ axcount is indicated for the treatment of essential hypertension (high blood pressure).

2. What you need to know before you take Kaliumlosartan HCTZ axcount

Do not take Kaliumlosartan HCTZ axcount

- if you are allergic to losartan, hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other sulfonamide-derived substances (e.g. other thiazides, some antibacterial drugs such as co-trimoxazole, ask your doctor if you are not sure)
- if you are more than 3 months pregnant. (It is also better to avoid Kaliumlosartan HCTZ axcount in early pregnancy - see section 2. 'Pregnancy, breast-feeding and fertility')
- if you have severely impaired liver function
- if you have severely impaired kidney function or your kidneys are not producing any urine.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- if you are suffering from gout

Warnings and precautions

You must tell your doctor if you think you are (or might become) pregnant. Kaliumlosartan HCTZ account is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see section 2. ‘Pregnancy, breast-feeding and fertility’).

Talk to your doctor, pharmacist or nurse before taking Kaliumlosartan HCTZ account:

- if you have previously suffered from swelling of the face, lips, throat or tongue,
- if you take diuretics (water pills),
- if you are on a salt-restricted diet,
- if you have or have had severe vomiting and/or diarrhoea,
- if you have heart failure,
- if your liver function is impaired (see section 2. ”Do not take Kaliumlosartan HCTZ account),
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant,
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function),
- if you have ‘aortic or mitral valve stenosis’ (narrowing of the valves of the heart) or ‘hypertrophic cardiomyopathy’ (a disease causing thickening of heart muscle),
- if you are diabetic,
- if you have had gout,
- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus),
- if you have high calcium or low potassium levels or you are on a low potassium diet,
- if you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets,
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- 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 Kaliumlosartan HCTZ account
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren.
- 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 Kaliumlosartan HCTZ account. 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.
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Kaliumlosartan HCTZ account, seek medical attention immediately.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take Kaliumlosartan HCTZ account”.

Other medicines and Kaliumlosartan HCTZ account

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Diuretic agents such as the hydrochlorothiazide contained in Kaliumlosartan HCTZ account may interact with other medicines.

Preparations containing lithium should not be taken with Kaliumlosartan HCTZ account without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics (“water tablets”), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

It is also important for your doctor to know if you are taking:

- other medicines to reduce your blood pressure,
- steroids,
- medicines to treat cancer,
- pain killers,
- drugs for treatment of fungal infections,
- arthritis medicines,
- resins used for high cholesterol, such as colestyramine,
- medicines which relax your muscles,
- sleeping tablets,
- opioid medicines such as morphine,
- ‘pressor amines’ such as adrenaline or other drugs from the same group,
- oral agents for diabetes or insulins.

Your doctor may need to change your dose and/or to take other precautions if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Kaliumlosartan HCTZ account” and “Warnings and precautions”).

Please also inform your doctor while you are taking Kaliumlosartan HCTZ account if you will be undergoing a radiographic procedure and will be given iodine contrast media.

Kaliumlosartan HCTZ account with food, drink and alcohol

You are advised not to drink alcohol whilst taking these tablets: alcohol and Kaliumlosartan HCTZ account tablets may increase each other’s effects.

Dietary salt in excessive quantities may counteract the effect of Kaliumlosartan HCTZ account tablets.

Kaliumlosartan HCTZ account tablets may be taken with or without food.

Pregnancy, breast-feeding and fertility

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

You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking Kaliumlosartan HCTZ account before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Kaliumlosartan HCTZ account. Kaliumlosartan HCTZ account is not recommended in early pregnancy, and must not be taken when more than 3 month pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Kaliumlosartan HCTZ axcount is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Children and adolescents

There is no experience with the use of Kaliumlosartan HCTZ axcount in children. Therefore, Kaliumlosartan HCTZ axcount should not be given to children.

Driving and using machines

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

Kaliumlosartan HCTZ axcount contains lactose monohydrate

Kaliumlosartan HCTZ axcount contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

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

3. How to take Kaliumlosartan HCTZ axcount

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

Your doctor will decide on the appropriate dose of Kaliumlosartan HCTZ axcount depending on your condition and whether you are taking other medicines. It is important to continue taking Kaliumlosartan HCTZ axcount for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

The tablet should be swallowed with a glass of water.

The tablets can be taken with or without food.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

The recommended dose is:

High Blood Pressure

The usual dose of Kaliumlosartan HCTZ axcount for most patients with high blood pressure is 1 tablet of Kaliumlosartan HCTZ axcount 50 mg/12.5 mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Losartan/Hydrochlorothiazide 50 mg/12.5 mg Film-Coated Tablets or changed to 1 tablet daily of Losartan/Hydrochlorothiazide 100 mg/25 mg Film-Coated Tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan/Hydrochlorothiazide 50 mg/12.5 mg Film-Coated Tablets or 1 tablet daily of Losartan Hydrochlorothiazide 100 mg/25 mg Film-Coated Tablets.

Use in children and adolescents

There is no experience with the use of Kaliumlosartan HCTZ axcount in children. Therefore, Kaliumlosartan HCTZ axcount should not be given to children.

Use in elderly patients

Kaliumlosartan HCTZ account works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

If you take more Kaliumlosartan HCTZ account than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take Kaliumlosartan HCTZ account

Try to take Kaliumlosartan HCTZ account daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

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.

If you experience the following, stop taking Kaliumlosartan HCTZ account tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

The side effects of medicines are classified as follows:

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data

The following side effects have been reported:

Common:

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder,
- Diarrhoea, abdominal pain, nausea, indigestion,
- Muscle pain or cramps, leg pain, back pain,
- Insomnia, headache, dizziness,
- Weakness, tiredness, chest pain,
- Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels,
- Changes in kidney function including kidney failure,
- Too low sugar in the blood (hypoglycaemia).

Uncommon:

- Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets,

- Loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels,
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment,
- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting,
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow,
- Ringing, buzzing, roaring or clicking in the ears, vertigo,
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, “mini-stroke”), heart attack, palpitations,
- Inflammation of blood vessels, which is often associated with a skin rash or bruising,
- Sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion,
- Constipation, obstipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache,
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas,
- Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss,
- Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness,
- Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine,
- Decreased sexual appetite, impotence,
- Swelling of the face, localised swelling (oedema), fever.

Rare:

- Hepatitis (inflammation of the liver), abnormal liver function tests.

Very rare

- *Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).*

Not known:

- Flu-like symptoms,
- Unexplained muscle pain with dark (tea-colored) urine (rhabdomyolysis),
- Low levels of sodium in the blood (hyponatraemia),
- Generally feeling unwell (malaise).
- 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)
- Skin and lip cancer (Non-melanoma skin cancer)

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Dutch Side effects Center Lareb website: www.lareb.nl.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kaliumlosartan HCTZ axcount

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

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

Do not store the package above 30° C.

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 to protect the environment.

6. Contents of the pack and other information

What Kaliumlosartan HCTZ axcount contains

- The active substances are losartan potassium and hydrochlorothiazide.
Kaliumlosartan HCTZ axcount 50 mg/12.5 mg contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide as the active ingredients.
Kaliumlosartan HCTZ axcount 100 mg/25 mg contains 100 mg of losartan potassium and 25 mg of hydrochlorothiazide as the active ingredients.
- The other ingredients are microcrystalline cellulose (E460a), lactose monohydrate, pregelatinized maize starch, sodium starch glycolate type A, magnesium stearate (E572), hydroxypropyl cellulose (E463), hypromellose 6cp (E464), titanium dioxide (E171).

What Kaliumlosartan HCTZ axcount looks like and the contents of the pack

Kaliumlosartan HCTZ axcount 50 mg/12.5 mg is supplied as white, oblong, biconvex tablets measuring approximately 13.7 × 6.7 mm with a scoreline on both sides.
The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Kaliumlosartan HCTZ axcount 100 mg/25 mg is supplied as white, oblong, biconvex tablets measuring approximately 15.3 × 6.7 mm with a scoreline on both sides.
The tablet can be divided into equal halves.

The tablets are provided in PVC/PE/PVDC/Aluminium blisters.

Pack sizes:

7, 10, 14, 20, 28, 30, 56, 56 (2x28), 60, 90, 98, 112 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

Kaliumlosartan HCTZ axcount 50/12,5 mg, filmomhulde tabletten; RVG 102223
Kaliumlosartan HCTZ axcount 100/25 mg, filmomhulde tabletten; RVG 102225

Deze bijsluiter is voor de laatste keer goedgekeurd in mei 2022.