Package leaflet: Information for the user

Lisinopril/Hydrochlorothiazide STADA 10/12.5 mg, tabletten
lisinopril 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 gets, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lisinopril/Hydrochlorothiazide <...> is and what it is used for

Lisinopril/Hydrochlorothiazide <...> is a combination of lisinopril and hydrochlorothiazide.

Lisinopril is a blood pressure lowering (antihypertensive) drug. It belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. It works by relaxing the blood vessels, making it easier for the blood to flow through them.

Hydrochlorothiazide is a water tablet belonging to the class of the thiazide diuretics. It makes the kidneys produce more urine and reduces thereby the blood volume.

Lisinopril/Hydrochlorothiazide <...> is used to:
- treat high blood pressure (essential hypertension).

Lisinopril/Hydrochlorothiazide <...> should be used in patients whose blood pressure is not adequately controlled on lisinopril alone (or hydrochlorothiazide alone).

2. What you need to know before you take Lisinopril/Hydrochlorothiazide <...>

DO NOT take Lisinopril/Hydrochlorothiazide <...>
- if you are allergic to lisinopril, other ACE inhibitors or to any of the other ingredients of this medicine (listed in section 6. “Contents of the pack and other information” at the end of this leaflet)
- if you are allergic (hypersensitive) to hydrochlorothiazide or other sulphonamides (medicines chemically related to hydrochlorothiazide)
- if you have previously suffered from angioedema (swelling of the skin and mucosa, especially in the face, mouth, tongue or throat with difficulty in swallowing or breathing) in connection with an ACE inhibitor

- if someone of your blood relatives has had angioedema (the predisposition may run in the family) or you have had angioedema in any other circumstances or from any other cause.
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.
- if you have severe kidney disease (creatinine clearance < 30 ml/min)
- you have stopped passing urine (anuria).if you have severe liver disease
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you are more than 3 months pregnant. (It is also better to avoid Lisinopril/Hydrochlorothiazide <...> in early pregnancy – see pregnancy section.)

Warnings and precautions
Talk to your doctor or pharmacist before taking Lisinopril/Hydrochlorothiazide <...>, especially:
- if you have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- if you are at risk of an excessive drop in blood pressure because you are suffering from salt and/or fluid depletion, for example because you are taking a urine output-increasing medicine or dialysis or are on a low-salt diet or as a result of vomiting and diarrhoea
- if you have a severe form of high blood pressure caused by a kidney disease (renin-dependent hypertension)
- if the heart valves of your left ventricle are narrowed, or other outflow obstructions from the left ventricle exist
- if you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- if you have a heart failure
- if you suffer from a heart disease with blood-flow disturbances of the coronary arteries (coronary heart disease)
- if you suffer from blood-flow disturbances of the brain (cerebrovascular disease)
- if your kidney function is moderately impaired
- if you have a narrowing of the kidney arteries
- if you have recently undergone a kidney transplant
- if your liver function is impaired or you suffer from hepatic disease
- if your liver enzyme values increase or you develop jaundice during treatment with Lisinopril/Hydrochlorothiazide <...>
- if you have high levels of cholesterol and you are having a treatment called ‘LDL apheresis’.
- if you have a condition called systemic lupus erythematosus (SLE).if changes in the number of blood cells occur during treatment with Lisinopril/Hydrochlorothiazide <...>:
  - if the number of your white blood cells (leukopenia) decreases
  - if the number of your red blood cells (anaemia) decreases
  - if the number of your platelets in blood (thrombocytopenia) decreases
  - or if a high-grade lessening of certain white blood cells with susceptibility to infection and severe general symptoms (agranulocytosis) develops
- if you suffer from a certain disease of the connective tissue (collagenosis) involving the blood vessels (collagen vascular disease)
- if you are being treated with medicines that suppresses your immune response
- if you are taking allopurinol (medicine for gout), procainamide (medicine for heart rhythm disturbances) or lithium (medicine for certain types of depression) at the same time. The use of Lisinopril/Hydrochlorothiazide <...> with lithium is not recommended.
- if you get hypersensitivity reactions (allergies) or tissue swelling (angioedema) during treatment with Lisinopril/Hydrochlorothiazide <...>
- if you are taking any of the following medicines, the risk of angioedema may be increased:
  - racecadotril, a medicine used to treat diarrhoea
  - medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus)
  - vildagliptin, a medicine used to treat diabetes

- if you need to have surgery and will be given a general or spinal anaesthetic; tell your doctor, dentist or hospital staff
- if you need dialysis with certain dialysis membranes (high-flux membranes), blood separation treatment for severely raised blood fats (apheresis) or desensitisation treatment for an allergy (e.g. to bee or wasp stings); your doctor may wish to interrupt your Lisinopril/Hydrochlorothiazide <...> treatment to prevent a possible allergic reaction
- if you suffer from diabetes
- if you suffer from gout
- if you get a stubborn, dry cough
- if you are at risk of a raise in potassium values in the blood e.g. if you
  - are taking potassium-containing salt substitutes, potassium-sparing diuretics, potassium supplements
  - are taking other drugs, associated with an increase in serum potassium
- if, based on your belonging to a certain ethnic group, the lowering of blood pressure is not sufficiently strong (particularly in patients with black skin)
  Please inform your doctor in this case.
- if you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
  - aliskiren
- 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 Lisinopril/Hydrochlorothiazide <...>
- 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 Lisinopril/Hydrochlorothiazide <...>. 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 Lisinopril/Hydrochlorothiazide <...>, 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 Lisinopril/Hydrochlorothiazide <...>”

While taking Lisinopril/Hydrochlorothiazide <...>
If you develop any of the following symptoms you should let your doctor know immediately:
- You feel dizzy after your first dose. A few people react to their first dose or when their dose is increased by feeling dizzy, weak, faint and sick.
- Complaints such as dry mouth, thirst, weakness, lethargy, muscle pain or cramps, racing heart, dizziness, nausea, vomiting and lessened urine production may be the sign of a disturbed fluid or mineral balance.
- Sudden swelling of the lips and face, neck, possibly also hands and feet, difficulty to swallow, hives and difficulties to breath, or wheezing or hoarseness. This condition is called angioedema. This may occur at any time during treatment. ACE inhibitors cause a higher rate of angioedema in black patients than in non-black patients.
- High temperature, sore throat or mouth ulcers (these may be symptoms of infection caused by the lowering of the number of white blood cells).
- Yellowing of the skin and whites of eyes (jaundice) that may be sign of liver disease.

In these cases, stop taking Lisinopril/Hydrochlorothiazide <...> and contact your doctor immediately. Your doctor will take appropriate measures.

At the beginning of treatment and/or during the period of dosage adjustment, increasing the frequency of medical check-ups may be necessary. You should not skip these visits even if you feel well. Your doctor will determine the frequency of control examinations.

If your blood pressure falls too much, you should lie down. If this persists, contact your doctor or nearest hospital casualty department immediately. The doctor may initiate a certain treatment to correct your hypotension.

Please talk to your doctor if your blood pressure sinks too much or frequently. This is important, as the doctor may decide to change your treatment.

Pregnancy
You must tell your doctor if you think that you are (or might become) pregnant.

Lisinopril/Hydrochlorothiazide <...> 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 Pregnancy and breast-feeding).

Anti-doping test
The hydrochlorothiazide contained in the medicine may produce a positive examination result in the anti-doping test.

Increase of certain metabolites in the blood
The level of following metabolites in the blood may increase due to the effects of hydrochlorothiazide also:
- cholesterol (hypercholesterolaemia)
- triglycerides (hypertriglyceridaemia)
- urea (hyperuricaemia).

Children
Lisinopril/Hydrochlorothiazide <...> should not be given to children, as the safety and efficacy of lisinopril/hydrochlorothiazide have not been established in this age group.

Other medicines and Lisinopril/Hydrochlorothiazide <...>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please check with your doctor if you are taking any of the following medicines, as their effect or the effect of Lisinopril/Hydrochlorothiazide <...> may be changed:

Potassium supplements (including salt substiutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
Your doctor will check your potassium values regularly.

Other urine output-increasing medicines (diuretics)
Increased lowering blood pressure.

Other blood pressure lowering medicines (antihypertensive agents), blood vessel-widening medicines (nitrates)
Increased lowering blood pressure.

Aliskiren and angiotensin II receptor blockers, medicines used to treat high blood pressure.
Your doctor may need to change your dose and/or to take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “DO NOT take Lisinopril/Hydrochlorothiazide <...>” and “Warnings and precautions”)

Increased risks of hypotension, syncope, hyperkalaemia, and changes in renal function (including acute renal failure)

Medicines for depression, as well as for other psychiatric diseases (tricyclic antidepressants, antipsychotics), narcotics, anaesthetics
Blood pressure lowered further. Increased lowering blood pressure.

Lithium (medicine for certain types of depression)
Raised risk of lithium poisoning. Using Lisinopril/Hydrochlorothiazide <...> and lithium at the same time is not recommended. Should this combination be necessary, however, lithium levels in the blood must be regularly monitored by the doctor.

Medicines for pain and inflammation (non-steroidal anti-inflammatories) including acetylsalicylic acid (doses from 3 g/day)
Concomitant use may reduce the blood pressure lowering effect and may lead to an elevation of serum potassium values in the blood, deterioration of kidney function; rarely, acute kidney failure, especially in patients with impaired kidney function.
Weakening of the diuretic and blood pressure lowering effect of hydrochlorothiazide.

Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.
Raised risk of symptoms like flushing, nausea, dizziness and hypotension, which can be very severe.

Sympathomimetics (agents with a stimulant effect e.g., raising of blood pressure)
Weakening of the blood pressure lowering effect.

Colestyramine and colestipol (active substances for lowering blood-fat values)
Weakening of the blood pressure-lowering effect. Absorption of hydrochlorothiazide delayed and reduced.

Blood sugar lowering medicines and insulin
Blood glucose lowered further with the risk of hypoglycaemia.

Amphotericin B (active substance against fungal infections), carbenoxolone (active substance for the treatment of gastrointestinal ulcers), cortisone-containing medicines (corticosteroids), corticotropin (a hormone acting on the adrenal glands) or certain laxatives
Disturbances of the mineral balance, e.g., lowered potassium values.

Calcium salts
Elevated serum calcium levels in the blood.

Cardiac glycosides (e.g., digoxin, active substance for strengthen the output of the heart)
Increased effects and side effects of the cardiac glycosides.

Muscle relaxants, e.g. tubocurarine chloride (active substances for relaxing muscles)
Muscle relaxant effect increased and prolonged.

Medicines associated with “torsade des pointes”, a dangerous type of heart rhythm disturbance
The risk of torsade de pointes is increased when potassium levels are low.

Allopurinol (active substance to treat gout)

Increases the risk of acute kidney failure and may lead to an increased risk of low number of white blood cells (leukopenia).

Ciclosporin (immunosuppressant used in organ transplantations)
Increases the risk of acute kidney failure and rises potassium concentrations in the blood.

Lovastatin (active substance to lower cholesterol)
Rises potassium concentrations in the blood.

Procainamide (active substance to treat irregular heart beat), cytostatic medicines (to treat cancer), immunosuppressive medicines (to avoid rejection of a transplanted organ)
May lead to an increased risk of low number of white blood cells (leukopenia)

Sotalol (to treat irregular heart beat and high blood pressure)
Increased risk of sotalol-induced arrhythmias (irregular heart beat)

Trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole (antibiotics)
Increased risk of hyperkalaemia (high blood potassium levels).

Haemodialysis
You should not take Lisinopril/Hydrochlorothiazide <...> if you are on haemodialysis. There is an increased risk of allergic reactions associated with certain types of dialysis membranes (see section “Warnings and precautions” above).

mTOR inhibitors
Medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section “Warnings and precautions”.

Lisinopril/Hydrochlorothiazide <...> with food and drink
Lisinopril/Hydrochlorothiazide <...> can be taken with or without food.

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

Appropriate antihypertensive drug must usually replace Lisinopril/Hydrochlorothiazide <...> before starting a pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Lisinopril/Hydrochlorothiazide <...> is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines
Like other blood pressure lowering medicines, Lisinopril/Hydrochlorothiazide <...> may reduce your ability to drive or use machines. Occasionally dizziness or tiredness may occur. This is more likely to occur at the beginning of the treatment, dose adjustment or in combination with

alcohol. These effects depend on your susceptibility. If affected, you must not drive or use machines.

3. How to take Lisinopril/Hydrochlorothiazide <...>

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

The suitable dose of Lisinopril/Hydrochlorothiazide <...> depends on the severity of your disease, your response to each active substance, the dosage of previous treatments (for example with lisinopril alone) and the function of your kidneys.

You doctor may prescribe you Lisinopril/Hydrochlorothiazide <...> 10/12.5 mg tablets if your blood pressure is not adequately controlled by 10 mg lisinopril alone.

Take the Lisinopril/Hydrochlorothiazide <...> tablet with a sufficient amount of water. You can take the tablet before, during or after meals.

The recommended dose is...

Adults
Take one Lisinopril/Hydrochlorothiazide <...> tablet daily. The tablet should be administered every day at roughly the same time.

You should not take more than 40 mg lisinopril/25 mg hydrochlorothiazide per day.

Older people
Older people with normal kidney function may take the same dose as adults.

Use in children
Lisinopril/Hydrochlorothiazide <...> should not be given to children, as the safety and efficacy of lisinopril/hydrochlorothiazide have not been established in this age group.

Patients with impaired kidney function
You must not take Lisinopril/Hydrochlorothiazide <...> if you suffer from a severe impairment of the kidney function (creatinine clearance < 30 ml/min).

If you suffer from a moderate impairment of the kidney function (creatinine clearance between 30 and 80 ml/min), your doctor will decide whether you may take Lisinopril/Hydrochlorothiazide <...> or not. He/she will also adjust your dose more carefully. The appropriate dose for you will depend on your response to lisinopril and hydrochlorothiazide alone.

If you take more Lisinopril/Hydrochlorothiazide <...> than you should
If you take too many tablets, contact your doctor or nearest hospital casualty department immediately for advice.
The symptoms of overdosage include low blood pressure (hypotension), circulatory shock, disturbances of the electrolyte balance (such as low levels of potassium, chloride and sodium in the blood), dehydration, kidney failure, overbreathing (hyperventilation), fast heart beat (tachycardia), feeling the heart beat (palpitations), lower heart rate (bradycardia), dizziness, anxiety and cough.

If you forget to take Lisinopril/Hydrochlorothiazide <...>
Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Lisinopril/Hydrochlorothiazide <...>
Do not stop taking Lisinopril/Hydrochlorothiazide <...> without first asking your doctor, even though you feel better.

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.

Important side effects or signs that you should pay attention to, and measures if you are affected
- If you get **tissue swelling** (angioneurotic oedema) in the region of the larynx, the vocal apparatus and/or the tongue, please notify your doctor immediately so that they can treat you with emergency medicines.
- If you notice that you have signs of **jaundice** (yellowing of the skin and the whites of the eyes, dark coloured urine) or a loss of appetite, you must interrupt treatment and inform your doctor immediately.
- If fever, **swollen lymph nodes and/or throat inflammation** occurs, notify your doctor at once so that they can examine the white blood count.
- Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion) - frequency very rare (may affect up to 1 in 10,000 people).

Some side effects may be warning signs of changes of chemicals in the blood (see section 2 “Warnings and precautions” above).
You should tell your doctor if you have any of the following warning signs of changes in the chemicals in the blood:
- dry mouth
- thirst
- weakness
- lack of energy (lethargy)
- drowsiness
- restlessness
- muscle pain (myalgia) or muscle cramps
- muscle fatigue
- low blood pressure (hypotension)
- decrease in the amount of urine (oliguria)
- fast heart beat (tachycardia)
- gastrointestinal disorders, such as feeling sick (nausea) and vomiting

The following side effects have been reported:

Common (may affect up to 1 in 10 people):
- dizziness, which generally betters after dose reduction and seldom requires discontinuation of the treatment
- headache
- fainting (syncope)
- tiredness (fatigue)
- dry and persistent cough, which disappears after stopping the treatment
- low blood pressure (hypotension), including orthostatic hypotension (fall in the blood pressure on standing up).
- If your blood pressure falls too much, you should lie down. If this persists, contact your doctor or nearest hospital casualty department immediately (see also section 2 “Warnings and precautions” above).

- diarrhoea
- vomiting
- disturbance of the kidney function (renal dysfunction)

Uncommon (may affect up to 1 in 100 people):
- gout
- feeling of pins and needles (paraesthesia)
- general weakness (asthenia)
- palpitations (feeling the heart beat)
- chest pain
- muscle spasms (painful and involuntary muscular contractions)
- muscle weakness
- feeling sick (nausea)
- indigestion
- abdominal pain
- inflammation of the pancreas (pancreatitis)
- dry mouth
- rash
- impotence
- mood alterations
- feeling of dizziness or spinning (vertigo)
- taste disturbance
- sleep disturbances
- heart attack (myocardial infarction) or stroke (cerebrovascular accident), possibly secondary to extremely low blood pressure (hypotension) in high risk patients (see section 2)
- fast heart beat (tachycardia)
- discolouration of fingers and toes (Raynaud's phenomenon)
- irritation and inflammation of the nose (rhinitis)
- itching (pruritus)
- high level of urea in the blood (hyperuricaemia)
- high level of creatinine in the blood, which may indicate an impaired kidney function. This usually disappears after stopping the treatment.
- altered liver function tests (increases in liver enzymes and in serum bilirubin)
- high level of potassium in the blood (hyperkalaemia)

Rare (may affect up to 1 in 1,000 people):
- hypersensitivity (allergic) reactions/angioedema (swelling of the skin and mucosa, of the face, limbs, lips, tongue and throat/voice box).
- You should stop taking Lisinopril/Hydrochlorothiazide <...> and contact your doctor immediately if you experience any symptoms of angioedema (see section 2. "Warnings and precautions").
- a complex of symptoms consisting of one or more of the following: fever, inflammation of the blood vessels (vasculitis), muscle pain (myalgia), joint pain (arthralgia) or inflammation of the joints (arthritis), positive ANA (anti-nuclear antibodies) test (a blood test to detect autoimmune diseases), increased erythrocyte sedimentation rate (a sign of inflammation in the body, detected by a blood test), high number of white blood cells (leukocytosis), including eosinophil granulocytes (eosinophilia), rash, sensitivity to sunlight (photosensitivity) or other skin reactions
- extremely low number of a certain type of white blood cells called granulocytes (agranulocytosis), which makes you more prone to infections. A clear relation between treatment with lisinopril/hydrochlorothiazide and agranulocytosis has not been established yet.
- haemolytic anaemia (anaemia caused by an abnormal breakdown of red blood cells)

- small decreases in haemoglobin and haematocrit (red blood cells) levels, which may lead to anaemia. These were frequently reported in patients with high blood pressure, but were rarely of clinical importance, unless other anaemia causes existed.
- mental confusion
- hives (urticaria)
- hair loss (alopecia)
- psoriasis (a skin disease which causes red patches and inflammation of the skin)
- uraemia (a toxic condition caused by kidney failure and characterised by accumulation of urea in the blood)
- acute kidney failure
- breast growth in men (gynaecomastia)
- excessive release of an hormone which can cause headache, feeling sick and being sick (syndrome of inappropriate antidiuretic hormone secretion)
- low level of sodium in the blood (hyponatraemia)

Very rare (may affect up to 1 in 10,000 people):
- bone marrow depression (when the bone marrow cannot make enough blood cells), which manifests itself as low number of red blood cells (anaemia), low number of blood platelets (thrombocytopenia) and/or low number of white blood cells (leukopenia)
- low number of a certain type of white blood cells called neutrophil granulocytes (neutropenia)
- enlargement of the lymph nodes (lymphadenopathy)
- autoimmune disease
- low blood sugar level (hypoglycaemia)
- bronchospasm (tightness of the chest that causes difficulty breathing and makes you wheeze)
- inflammation of the cavities of the nose (sinusitis)
- inflammation of the alveoli of the lungs caused by allergy (allergic alveolitis)
- accumulation of white blood cells (eosinophils) in the lungs (eosinophilic pneumonia)
- swelling of the mucosa of the gut (intestinal angioedema)
- inflammation of the liver (hepatitis)
- jaundice (yellowing of the skin and the whites of the eyes, mostly due to a liver disease).
- If you develop jaundice, you should stop taking Lisinopril/Hydrochlorothiazide <...> and contact your doctor immediately.
- liver failure
- increased sweating (diaphoresis)
- pemphigus (an autoimmune disease which causes blistering and raw sores on the skin)
- toxic epidermal necrolysis (a very serious skin disorder which causes loss of large areas of skin)
- Stevens-Johnson syndrome (a severe skin disorder characterised by peeling of the skin)
- erythema multiforme (a skin condition with itchy pink-red blotches)
- decreased or absent production of urine (oliguria or anuria)

Not known (frequency cannot be estimated from the available data):
- Lisinopril/Hydrochlorothiazide <...> may alter the results of blood tests. These alterations can rarely have a clinical importance.
- high blood sugar level (hyperglycaemia)
- low level of potassium in the blood (hypokalaemia)
- high level of cholesterol in the blood
- high level of triglycerides in the blood
- inflammation of the salivary glands (sialadenitis)
- aplastic anaemia (when the bone marrow cannot make enough blood cells)
- loss of appetite (anorexia)
- presence of sugar in the urine (glucosuria)
- restlessness

- depression
- depressive symptoms
- light-headedness
- xanthopsia (yellow colouration of the vision)
- transient 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). If you have a suddenly painful red eye tell your doctor immediately; you may need treatment to avoid permanent loss of vision
- irregular heart beat (cardiac arrhythmias)
- sudden reddening of the face (flushing)
- inflammation of the blood vessels (angiitis/vasculitis [also cutaneous]), which may lead to tissue death (necrosis)
- difficulty breathing (respiratory distress), including inflammation of the lungs (pneumonitis) and swelling and/or fluid accumulation in the lungs (pulmonary oedema)
- stomach irritation
- constipation
- sensitivity reactions to sunlight (photosensitivity)
- electrolyte imbalances (changes in the levels of water and chemicals in the blood)
- cutaneous lupus erythematosus-like reactions and activation or reactivation of cutaneous lupus erythematosus (an autoimmune disease which causes rash on the face (malar or butterfly rash) and red scaly patches on the skin)
- serious allergic (anaphylactic) reactions
- inflammation of the kidneys (interstitial nephritis)
- fever
- weakness
- skin and lip cancer (Non-melanoma skin cancer)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lisinopril/Hydrochlorothiazide <...>

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister 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 Lisinopril/Hydrochlorothiazide <...> contains
The active substances are lisinopril and hydrochlorothiazide.

Lisinopril/Hydrochlorothiazide <...> 10/12.5 mg:
Each Lisinopril/Hydrochlorothiazide <...> tablet contains lisinopril dihydrate (equivalent to 10 mg of lisinopril) and 12.5 mg of hydrochlorothiazide.

The other ingredients are:
- calcium hydrogen phosphate dihydrate (E341)
- magnesium stearate (E470b)
- maize starch
- mannitol (E421)
- colloidal anhydrous silica (E551)

What Lisinopril/Hydrochlorothiazide <...> looks like and contents of the pack
Lisinopril/Hydrochlorothiazide <...> tablets are white, round, biconvex, scored tablets with the imprint C 10 on one side.

Lisinopril/Hydrochlorothiazide <...> is available in cardboard packs containing 10, 14, 15, 20, 28, 30, 40, 50, 56, 60, 70, 80, 90, 98, 100, 200, 250, 400, 500 or 1000 tablets in PVC/PVDC/aluminium blisters.

Not all packaging sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Manufacturer
STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany
Centrafarm Services B.V., Van de Reijtstraat 31-E, 4814 NE Breda, The Netherlands

Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary, Ireland
Sanico N.V., Veedijk 59, Industriezone 4, B-2300 Turnhout, Belgium

In het register ingeschreven onder
RVG 29993 Lisinopril/Hydrochloorthiazide STADA 10/12,5 mg, tabletten

This medicine is authorised in the Member States of the EEA under the following names:
DE: Lisiplus AL 10 mg/12,5 mg Tabletten
NL: Lisinopril/Hydrochloorthiazide STADA10/12,5 mg tabletten/

Deze bijsluiter is voor het laatst goedgekeurd in december 2023.