

FLAT DIMENSION = 190 x 580mm

FOLDED DIMENSION = 190 x 36mm

**Package Leaflet: Information for the user**

**LISORETIC® 10 MG/12.5 MG TABLETS**  
**LISORETIC® 20 MG/12.5 MG TABLETS**

**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. See section 4.

**What is in this leaflet:**

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

**1. What this medicine is and what it is used for**

This medicine is used to treat high blood pressure (hypertension). It contains two medicines called lisinopril (as dihydrate) and hydrochlorothiazide.

- Lisinopril belongs to a group of medicines called ACE inhibitors. It works by making your blood vessels widen.
- Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). It helps your body to get rid of water and salts like sodium in your urine. These medicines work together to lower your blood pressure.

**2. What you need to know before you take this medicine**

**Do not take this medicine if:**

- You are allergic to lisinopril or hydrochlorothiazide or any of the other ingredients of this medicine (listed in Section 6).
- You are allergic to ACE inhibitor or sulphonamide medicines. If you are not sure if this applies to you, please ask your doctor.
- You have ever had sudden swelling of the hands, feet, ankles, face, lips, tongue or throat, especially if this followed treatment with an ACE inhibitor. It may also have been difficult to swallow or breathe.
- 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.
- You have hereditary angioedema (a condition that makes you more prone to the swelling described above). If you are not sure if this applies to you, please ask your doctor.
- You have severe kidney problems.
- You have stopped passing water (urine).
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- You have severe liver problems.
- You are more than 3 months pregnant (It is also better to avoid this medicine in early pregnancy - see pregnancy section).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

**Warnings and precautions**

Talk to your doctor, nurse or pharmacist before taking this medicine 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 this medicine.
- You have a narrowing (stenosis) of the aorta (an artery in your heart), the heart valves (mitral valves) or the kidney artery.
- You have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- You have problems with your blood vessels (collagen vascular disease).
- You have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- You have kidney problems or you are having kidney dialysis or you have had a kidney transplant.
- You have liver problems.
- You have diabetes.
- You have recently had diarrhoea or vomiting (being sick).
- Your doctor has told you to control the amount of salt in your diet.
- You have high levels of cholesterol and you are having a treatment called 'LDL apheresis'.
- You have ever had a condition called systemic lupus erythematosus (SLE).
- You are of black origin as this medicine may be less effective. You may also more readily get the side effect 'angioedema' (a severe allergic reaction with swelling of the hands, feet, ankles, face, lips, tongue or throat).
- 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 this medicine. 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.
- You are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
  - temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer).
  - Racecadotril, a medicine used to treat diarrhoea;
  - Vildagliptin, a medicine used to treat diabetes.
- 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 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 this medicine, 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 this medicine"

You must tell your doctor if you think you are (or might become) pregnant. This medicine 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 pregnancy, breast-feeding and fertility section). If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

**Treatment for allergies such as insect stings**

Tell your doctor if you are having or are going to have treatment to lower the effects of an allergy such as insect stings (desensitisation treatment). If you take this medicine while you are having this treatment, it may cause a severe allergic reaction.

**Operations**

If you are going to have an operation (including dental surgery) tell the doctor or dentist that you are taking this medicine. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking this medicine.

**Other medicines and this medicine**

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.** This includes medicines that you buy without a prescription and herbal medicines. This is because this medicine can affect the way some medicines work and some medicines can have an effect on this medicine. Your doctor may need to change your dose and/or to take other precautions.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines for treatment of high blood pressure (antihypertensives).
- An angiotensin II receptor blocker (ARB) or aliskiren, (see also information under the headings "Do not take this medicine" and "Warnings and precautions").
- Medicines associated with low blood potassium (hypokalaemia) such as other diuretics ("water tablets" including those which conserve potassium, laxatives, corticosteroids (e.g. prednisone), ACTH (A hormone), amphotericin (an antifungal medicine) and salicylic acid derivatives.
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen or indomethacin, used to treat muscle pain and arthritis.
- Medicines for depression (tricyclic and tetracyclic antidepressants).
- Medicines for mental problems, including lithium.
- Aspirin (acetylsalicylic acid), if you are taking more than 3 grams each day.
- Potassium supplements (including salt substitutes), 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).
- Calcium salts or Vitamin D supplements.
- Medicines for diabetes (insulin and oral antidiabetics such as sulfonylureas). Your dose of antidiabetic medicine may need to be changed when taking thiazide diuretics.
- Medicines to treat asthma.
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Medicines to suppress the body's immune response (immunosuppressants, such as ciclosporin).
- Allopurinol (for gout).
- Medicines for uneven heart beat problems (such as procainamide).
- Heart medicines (e.g. digoxin) or other medicines to control the rhythm of your heart.
- Gold injections (such as sodium aurothiomalate), usually used to treat rheumatoid arthritis.
- Amphotericin B injection (to treat fungal infections).
- Carbenoxolone (to treat ulcers or inflammation in the gullet or in and around the mouth).
- Corticosteroids (steroid medicines).
- Corticotropin (a hormone).
- Medicines to treat constipation (stimulant laxatives).
- Colestyramine and colestipol (to lower cholesterol, prevent diarrhoea or reduce itching)
- Muscle relaxants such as tubocurarine.
- Trimethoprim (an antibiotic).
- Sotalol (a beta-blocker).
- Medicines used to treat cancer (e.g. cyclophosphamide, methotrexate).
- Lovastatin (to lower cholesterol).
- Dextran sulphate (used in the treatment called 'LDL apheresis' to lower cholesterol).

The following medicines may increase the risk of angioedema (signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing):

- Medicines to break up blood clots (tissue plasminogen activator), usually given in hospital.
- Medicines which are most often used to avoid rejection of transplanted organs (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section 2 "Warnings and precautions".
- Racecadotril used to treat diarrhoea.
- Vildagliptin, a medicine used to treat diabetes.
- Other medicines known to have an effect on the heart called Torsades de pointes.
- Low blood pressure may be aggravated by alcohol, barbiturates or anaesthetics. You may notice dizziness when standing up.

Please note that when you are taking this medicine it may affect any tests your doctor may perform on blood or urine samples. Please remind your doctor you are taking this medicine if they ever want to carry out such a test.

**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 you are (or might become) pregnant. Your doctor will normally advise you to stop taking this medicine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of this medicine. This medicine is not recommended in early 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.

**Breast-feeding**

Tell your doctor if you are breast-feeding or about to start breast-feeding. This medicine 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**

- This medicine may cause occasional dizziness or tiredness which may have an effect on your ability to drive or use machines, especially at the start of treatment or when the dose is modified, or in combination with alcohol. If this happens to you, do not drive or use any tools or machines.
- You must wait to see how your medicine affects you before trying these activities.

**3. How to take this medicine**

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

Once you have started taking this medicine your doctor may take blood tests. Your doctor may then adjust your dose so you take the right amount of medicine for you.

**Taking your medicine**

- Swallow the tablet with a drink of water.
- Try to take your tablets at the same time each day. It does not matter if you take this medicine before or after food.
- Keep taking this medicine for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking this medicine everyday.

**Taking your first dose**

- Take special care when you have your first dose of this medicine or if your dose is increased. It may cause a greater fall in blood pressure than later doses.
- This may make you feel dizzy or light-headed. If this happens, it may help to lie down. If you are concerned, please talk to your doctor as soon as possible.

## Adults

- The recommended dose is one tablet once a day. Your doctor will prescribe the tablet that is the right strength for you.
- If necessary, your doctor may increase your dose to two tablets once a day.

## Use in Children

- This medicine is not recommended for use in children.

## If you take more of this medicine than you should

If you take more of this medicine than prescribed by your doctor, talk to a doctor or go to a hospital immediately. Take the medicine pack with you so that the tablets can be identified.

## If you forget to take this medicine

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

## If you stop taking this medicine

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you to. 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.

This medicine contains two medicines: lisinopril and hydrochlorothiazide. The following side effects have been seen with these individual medicines. This means they could also happen with this medicine.

Your doctor may take blood samples from time to time to check whether this medicine has had any effect on your blood.

## Possible side effects with lisinopril

**Severe allergic reactions** (rare, may affect up to 1 in 1,000 people)

**Stop taking this medicine**, if you have a severe allergic reaction, see a doctor immediately. The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet or ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

**Severe liver problems** (very rare, may affect up to 1 in 10,000 people)

The signs may include:

- Yellowing of your skin or eyes, (jaundice) dark coloured urine or a loss of appetite.

If this happens to you, **see a doctor immediately**.

## Other possible side effects:

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

- Headache
- Fainting
- Cough
- Diarrhoea, being sick (vomiting)
- Feeling dizzy or light headed, especially if you stand up quickly
- Kidney problems (shown in a blood test)

**Uncommon (may affect up to 1 in 100 people)**

- Mood changes including feeling depressed.
- Tingling feeling such as ‘pins and needles’.
- Changes in the way things taste.
- A very big drop in blood pressure may happen in people with the following conditions:

Coronary heart disease, narrowing of the aorta (a heart artery), kidney artery or heart valves, an increase in the thickness of the heart muscle. If this happens to you, you may feel dizzy or light headed, especially if you stand up quickly.

- Heart attack or stroke, unusual heart beat.
- Change of colour in your fingers or toes.
- Stomach pain and indigestion.
- Changes in blood tests that check how the liver is working.
- Being unable to get an erection (impotence).
- Increased levels of certain substances in your blood (urea, creatinine or potassium).
- Spinning feeling (vertigo).
- Difficulty in sleeping.
- Runny nose.
- Feeling sick (nausea).
- Itchiness, rashes.
- Feeling weak or tired

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

Changes to some of the cells or other parts of your blood. The signs may include

feeling tired and pale skin.

- Feeling confused.
- Hair loss (alopecia).
- Psoriasis (a skin problem).
- Infection of the blood.
- Kidney failure.
- Enlarged breasts in men
- Changes in the way things smell, dry mouth.
- Skin rash with dark red, raised, itchy bumps (hives).
- Syndrome of inappropriate antidiuretic hormone secretion (SIADH).
- Low levels of sodium in the blood, which may cause weakness, tiredness, headache, feeling sick, being sick (vomiting) and cramps.

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

- Problems with your bone marrow or a reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, sore throat, mouth ulcer, feeling breathless or that you bruise or bleed more easily.
- Swollen glands (lymph nodes).
- Increased immune response (autoimmune disease).
- Low levels of sugar in your blood (hypoglycaemia). The signs may include feeling hungry or weak, sweating and a fast heart beat.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Lung inflammation (which may make you feel breathless).
- Sinusitis (a feeling of pain and fullness behind your cheeks and eyes).
- Eosinophilic pneumonia. The signs include a combination of the following:
  - sinusitis
  - feeling like you have flu
  - feeling more and more breathless
  - pain in the area of your stomach or gut
  - skin rash
  - a feeling of ‘pins and needles’ or numbness of your arms or legs.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Swelling of the lining of the gut. This may cause sudden stomach pain, diarrhoea or make you be sick (vomit).
- Sweating.

- Severe skin disorder or rash. The symptoms include redness, blistering and peeling of the skin which may develop quickly and may include blistering in the mouth and nose.
- Passing less water (urine) than normal or passing no water.

**Not known (frequency cannot be estimated from the available data)**

- Seeing, feeling or hearing things that are not there (hallucinations).
- Flushing of your skin.

**Possible side effects with hydrochlorothiazide (frequency not known)**

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

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

**Not known (frequency cannot be estimated from the available data)**

- Skin and lip cancer (Non-melanoma skin cancer)
- A reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, feeling breathless or that you bruise or bleed more easily.
- An increase in the amount of sugar (glucose) in your blood (hyperglycaemia).
- Loss of appetite.
- Inflammation of a salivary gland.
- Sugar in your urine.
- Feeling restless.
- Depression.
- Difficulty sleeping.
- Tingling feelings such as ‘pins and needles’.
- Feeling light-headed.
- A spinning feeling (vertigo).
- Feeling faint (especially when standing up).
- Problems with your sight for a short time.

- Stomach irritation.
- Diarrhoea or constipation.
- Allergic reactions.
- Fever
- Weakness

- Muscle cramps and muscle weakness.
- An increase in the amount of uric acid in your blood.
- Altered levels of substances in your blood (for example low sodium and potassium). You may notice muscle weakness, thirst, ‘pins and needles’, cramps or feeling sick.
- Raised or high levels of fats in your blood (including cholesterol).
- Changes to your vision that can make things look yellow.
- Severe eye pain with redness and sudden blurred vision. If you have a suddenly painful red eye tell your doctor immediately; you may need treatment to avoid permanent loss of vision.
- Damage to blood vessels causing red or purple spots in the skin.
- Difficulty breathing. You may feel breathless if your lungs get inflamed or have fluid on them.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Yellowing of your skin or the whites of your eyes (jaundice).
- Skin problems including rash caused by sensitivity to sunlight, rash, severe rash that develops quickly with blistering or peeling of the skin and possibly blistering in the mouth, activating or worsening of existing lupus conditions or appearance of unusual skin reactions.
- Kidney problems which may be severe (shown in blood tests).
- 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)

Do not be concerned by this list of possible side effects. You may not get any of them.

## 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 the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 this medicine

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Do not throw away any medicines via waste water 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 this medicine contain

- The active substances are Lisinopril (as dihydrate) and Hydrochlorothiazide.
- This medicine come in two strengths, 10 mg/12.5 mg and 20 mg/12.5 mg. Each tablet contains either 10 mg of lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide or 20 mg lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide.

The other ingredients of the tablets are: calcium hydrogen phosphate, mannitol, maize starch, pregelatinised starch and magnesium stearate. 10 mg/12.5 mg tablets also contain ferric oxide red (E172) and ferric oxide yellow (E172).

## What this medicine looks like and contents of the pack

- 10 mg/12.5 mg tablets are light pink, circular, biconvex mottled uncoated tablets.
- 20 mg/12.5 mg tablets are white to off white, circular, biconvex uncoated tablets.
- This medicine come in packs containing 28 tablets.

## Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,  
Unit 3, Canalside, Northbridge Road, Berkhamsted,  
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Bristol Laboratories Ltd,  
Unit 5, Traynor Way, Whitehouse Business Park,  
Peterlee, SR8 2RU, United Kingdom.

**LISORETIC® 10 mg/12.5 mg Tablets; PL 17907/0073**  
**LISORETIC® 20 mg/12.5 mg Tablets; PL 17907/0074**

This leaflet was last revised in December 2022

To request a copy of this leaflet in Braille, large print or audio, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.

V36 23-12-22 D0



SAME SIZE ARTWORK

580 x 190mm

Back

**Package Leaflet: Information for the user**

**LISINAPRIL AND HYDROCHLOROTHIAZIDE 10 MG/12.5 MG TABLETS  
LISINAPRIL AND HYDROCHLOROTHIAZIDE 20 MG/12.5 MG TABLETS**

**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. See section 4.

**What is in this leaflet:**

1. What Lisinopril and Hydrochlorothiazide Tablets are and what they are used for
2. What you need to know before you take Lisinopril and Hydrochlorothiazide Tablets
3. How to take Lisinopril and Hydrochlorothiazide Tablets
4. Possible side effects
5. How to store Lisinopril and Hydrochlorothiazide Tablets
6. Contents of the pack and other information

**1. What Lisinopril and Hydrochlorothiazide Tablets are and what they are used for**

Lisinopril and Hydrochlorothiazide is used to treat high blood pressure (hypertension). It contains two medicines called lisinopril (as dihydrate) and hydrochlorothiazide.

- Lisinopril belongs to a group of medicines called ACE inhibitors. It works by making your blood vessels widen.
  - Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). It helps your body to get rid of water and salts like sodium in your urine.
- These medicines work together to lower your blood pressure.

**2. What you need to know before you take Lisinopril and Hydrochlorothiazide Tablets**

**Do not take Lisinopril and Hydrochlorothiazide Tablets if:**

- You are allergic to lisinopril or hydrochlorothiazide or any of the other ingredients of Lisinopril and Hydrochlorothiazide (listed in Section 6).
- You are allergic to ACE inhibitor or sulphonamide medicines. If you are not sure if this applies to you, please ask your doctor.
- You have ever had sudden swelling of the hands, feet, ankles, face, lips, tongue or throat, especially if this followed treatment with an ACE inhibitor. It may also have been difficult to swallow or breathe.
- 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.
- You are taking aliskiren.
- You have hereditary angioedema (a condition that makes you more prone to the swelling described above). If you are not sure if this applies to you, please ask your doctor.
- You have severe kidney problems.
- You have stopped passing water (urine).
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- You have severe liver problems.
- You are more than 3 months pregnant. It is also better to avoid Lisinopril and Hydrochlorothiazide in early pregnancy - see pregnancy section.

Do not take Lisinopril and Hydrochlorothiazide if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Lisinopril and Hydrochlorothiazide.

**Warnings and precautions**

Talk to your doctor, nurse or pharmacist before taking this medicine 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 this medicine.
- You have a narrowing (stenosis) of the aorta (an artery in your heart), the heart valves (mitral valves) or the kidney artery.
- You have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- You have problems with your blood vessels (collagen vascular disease).
- You have low blood pressure. You may notice this as feeling dizzy or light-headed, especially when standing up.
- You have kidney problems or you are having kidney dialysis or you have had a kidney transplant.
- You have liver problems.
- You have diabetes.
- You have recently had diarrhoea or vomiting (being sick).
- Your doctor has told you to control the amount of salt in your diet.
- You have high levels of cholesterol and you are having a treatment called ‘LDL apheresis’.
- You have ever had a condition called systemic lupus erythematosus (SLE).
- You are of black origin as this medicine may be less effective. You may also more readily get the side effect ‘angioedema’ (a severe allergic reaction with swelling of the hands, feet, ankles, face, lips, tongue or throat).
- 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 this medicine. 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.
- You are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
  - temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer).
  - Racecadotril, a medicine used to treat diarrhoea;
  - Vildagliptin, a medicine used to treat diabetes.
- 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 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 this medicine, 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 and Hydrochlorothiazide Tablets”.

You must tell your doctor if you think you are (or might become) pregnant. Lisinopril and 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 pregnancy, breast-feeding and fertility section).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Lisinopril and Hydrochlorothiazide.

**Treatment for allergies such as insect stings**

Tell your doctor if you are having or are going to have treatment to lower the effects of an allergy such as insect stings (desensitisation treatment). If you take Lisinopril and Hydrochlorothiazide while you are having this treatment, it may cause a severe allergic reaction.

**Operations**

If you are going to have an operation (including dental surgery) tell the doctor or dentist that you are taking Lisinopril and Hydrochlorothiazide. This is because you can get low blood pressure (hypotension) if you are given certain local or general anaesthetics while you are taking Lisinopril and Hydrochlorothiazide.

**Other medicines and Lisinopril and Hydrochlorothiazide Tablets**

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.** This includes medicines that you buy without a prescription and herbal medicines. This is because Lisinopril and Hydrochlorothiazide can affect the way some medicines work and some medicines can have an effect on Lisinopril and Hydrochlorothiazide. Your doctor may need to change your dose and/or to take other precautions.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines for treatment of high blood pressure (antihypertensives).
- An angiotensin II receptor blocker (ARB) or aliskiren, (see also information under the headings “Do not take this medicine” and “Warnings and precautions”).
- Medicines associated with low blood potassium (hypokalaemia) such as other diuretics (“water tablets” including those which conserve potassium, laxatives, corticosteroids (e.g. prednisone), ACTH (A hormone), amphotericin (an antifungal medicine) and salicylic acid derivatives.
- Non-steroidal anti inflammatory drugs (NSAIDs) such as aspirin, ibuprofen or indomethacin, used to treat muscle pain and arthritis.
- Medicines for depression (tricyclic and tetracyclic antidepressants).
- Medicines for mental problems, including lithium.
- Aspirin (acetylsalicylic acid), if you are taking more than 3 grams each day.
- Potassium supplements (including salt substitutes), 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).
- Calcium salts or Vitamin D supplements.
- Medicines for diabetes (insulin and oral antidiabetics such as sulfonylureas). Your dose of antidiabetic medicine may need to be changed when taking thiazide diuretics.
- Medicines to treat asthma.
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Medicines to suppress the body’s immune response (immunosuppressants, such as ciclosporin).
- Allopurinol (for gout).
- Medicines for uneven heart beat problems (such as procainamide).
- Heart medicines (e.g. digoxin) or other medicines to control the rhythm of your heart.
- Gold injections (such as sodium aurothiomalate), usually used to treat rheumatoid arthritis.
- Amphotericin B injection (to treat fungal infections).
- Carbenoxolone (to treat ulcers or inflammation in the gullet or in and around the mouth).
- Corticosteroids (steroid medicines).
- Corticotropin (a hormone).
- Medicines to treat constipation (stimulant laxatives).
- Colestyramine and colestipol (to lower cholesterol, prevent diarrhoea or reduce itching).
- Muscle relaxants such as tubocurarine.
- Trimethoprim (an antibiotic).
- Sotalol (a beta-blocker).

- Lovastatin (to lower cholesterol).
- Medicines used to treat cancer (e.g. cyclophosphamide, methotrexate).
- Dextran sulphate (used in the treatment called ‘LDL apheresis’ to lower cholesterol).

The following medicines may increase the risk of angioedema (signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing):

- Medicines to break up blood clots (tissue plasminogen activator), usually given in hospital.
- Medicines which are most often used to avoid rejection of transplanted organs (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section 2 “Warnings and precautions”.
- Racecadotril used to treat diarrhoea.
- Vildagliptin, a medicine used to treat diabetes.
- Other medicines known to have an effect on the heart called Torsades de pointes.
- Low blood pressure may be aggravated by alcohol, barbiturates or anaesthetics. You may notice dizziness when standing up.

Please note that when you are taking this medicine it may affect any tests your doctor may perform on blood or urine samples. Please remind your doctor you are taking this medicine if they ever want to carry out such a test.

**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 you are (or might become) pregnant. Your doctor will normally advise you to stop taking Lisinopril and 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 and Hydrochlorothiazide. Lisinopril and Hydrochlorothiazide is not recommended in early 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.

**Breast-feeding**

Tell your doctor if you are breast-feeding or about to start breast-feeding. Lisinopril and 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**

- This medicine may cause occasional dizziness or tiredness which may have an effect on your ability to drive or use machines, especially at the start of treatment or when the dose is adjusted, or in combination with alcohol. If this happens to you, do not drive or use any tools or machines.
- You must wait to see how your medicine affects you before trying these activities.

**3. How to take Lisinopril and Hydrochlorothiazide Tablets**

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

Once you have started taking Lisinopril and Hydrochlorothiazide your doctor may take blood tests. Your doctor may then adjust your dose so you take the right amount of medicine for you.

**Taking your medicine**

- Swallow the tablet with a drink of water.
- Try to take your tablets at the same time each day. It does not matter if you take this medicine before or after food.
- Keep taking Lisinopril and Hydrochlorothiazide for as long as your doctor tells you to, it is a long term treatment. It is important to keep taking Lisinopril and Hydrochlorothiazide every day.

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#### Taking your first dose

- Take special care when you have your first dose of Lisinopril and Hydrochlorothiazide or if your dose is increased. It may cause a greater fall in blood pressure than later doses.
- This may make you feel dizzy or light-headed. If this happens, it may help to lie down. If you are concerned, please talk to your doctor as soon as possible.

#### Adults

- The recommended dose is one tablet once a day. Your doctor will prescribe the tablet that is the right strength for you.
- If necessary, your doctor may increase your dose to two tablets once a day.

#### Use in Children

- Lisinopril and Hydrochlorothiazide is not recommended for use in children.

#### If you take more Lisinopril and Hydrochlorothiazide Tablets than you should

If you take more Lisinopril and Hydrochlorothiazide than prescribed by your doctor, talk to a doctor or go to a hospital immediately. Take the medicine pack with you so that the tablets can be identified.

#### If you forget to take Lisinopril and Hydrochlorothiazide Tablets

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Lisinopril and Hydrochlorothiazide Tablets

Do not stop taking your tablets, even if you are feeling well, unless your doctor tells you to.

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.

Lisinopril and Hydrochlorothiazide contains two medicines: lisinopril and hydrochlorothiazide. The following side effects have been seen with these individual medicines. This means they could also happen with Lisinopril and Hydrochlorothiazide.

Your doctor may take blood samples from time to time to check whether Lisinopril and Hydrochlorothiazide has had any effect on your blood.

#### Possible side effects with lisinopril

**Severe allergic reactions** (rare, may affect up to 1 in 1,000 people)

**Stop taking Lisinopril and Hydrochlorothiazide**, if you have a severe allergic reaction, see a doctor immediately. The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet or ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

**Severe liver problems** (very rare, may affect up to 1 in 10,000 people)

The signs may include:

- Yellowing of your skin or eyes, dark coloured urine or a loss of appetite. If this happens to you, see a doctor immediately.

#### Other possible side effects:

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

- Headache
- Fainting
- Cough
- Diarrhoea, being sick (vomiting)
- Feeling dizzy or light headed, especially if you stand up quickly
- Kidney problems (shown in a blood test)

**Uncommon (may affect up to 1 in 100 people)**

- Mood changes including feeling depressed.
- Tingling feeling such as ‘pins and needles’.
- Changes in the way things taste.
- A very big drop in blood pressure may happen in people with the following conditions: Coronary heart disease, narrowing of the aorta (a heart artery), kidney artery or heart valves, an increase in the thickness of the heart muscle. If this happens to you, you may feel dizzy or light headed, especially if you stand up quickly.
- Heart attack or stroke, unusual heart beat.
- Change of colour in your fingers or toes.
- Stomach pain and indigestion.
- Changes in blood tests that check how the liver is working.
- Being unable to get an erection (impotence).
- Increased levels of certain substances in your blood (urea, creatinine or potassium).
- Spinning feeling (vertigo).
- Difficulty in sleeping.
- Runny nose.
- Feeling sick (nausea).
- Itchiness, rashes.
- Feeling weak or tired

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

- Changes to some of the cells or other parts of your blood. The signs may include feeling tired and pale skin.
- Feeling confused.
- Hair loss (alopecia).
- Psoriasis (a skin problem).
- Infection of the blood.
- Kidney failure.
- Enlarged breasts in men
- Changes in the way things smell, dry mouth.
- Skin rash with dark red, raised, itchy bumps (hives).
- Syndrome of inappropriate antidiuretic hormone secretion (SIADH).
- Low levels of sodium in the blood, which may cause weakness, tiredness, headache, feeling sick, being sick (vomiting) and cramps.

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

- Problems with your bone marrow or a reduced number of blood cells and/ or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, sore throat, mouth ulcer, feeling breathless or that you bruise or bleed more easily.
- Swollen glands (lymph nodes).
- Increased immune response (autoimmune disease).
- Low levels of sugar in your blood (hypoglycaemia). The signs may include feeling hungry or weak, sweating and a fast heart beat.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Lung inflammation (causing breathing problems).
- Sinusitis (a feeling of pain and fullness behind your cheeks and eyes).
- Eosinophilic pneumonia. The signs include a combination of the following:
  - sinusitis
  - feeling like you have flu
  - feeling more and more breathless
  - pain in the area of your stomach or gut
  - skin rash

- a feeling of ‘pins and needles’ or numbness of your arms or legs.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Swelling of the lining of the gut. This may cause sudden stomach pain, diarrhoea or make you be sick (vomit).
- Sweating.
- Severe skin disorder or rash. The symptoms include redness, blistering and peeling of the skin which may develop quickly and may include blistering in the mouth and nose.
- Passing less water (urine) than normal or passing no water.

**Not known (frequency cannot be estimated from the available data)**

- Seeing, feeling or hearing things that are not there (hallucinations).
- Flushing of your skin.

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

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

**Not known (frequency cannot be estimated from the available data)**

**Possible side effects with hydrochlorothiazide (frequency not known)**

- Skin and lip cancer (Non-melanoma skin cancer)
- A reduced number of blood cells and/or platelets in your blood. You may notice tiredness, an infection (which may be serious), fever, feeling breathless or that you bruise or bleed more easily.
- An increase in the amount of sugar (glucose) in your blood (hyperglycaemia).
- Loss of appetite.
- Inflammation of a salivary gland.
- Sugar in your urine.
- Feeling restless.
- Depression.
- Difficulty sleeping.
- Tingling feelings such as ‘pins and needles’.
- Feeling light-headed.
- A spinning feeling (vertigo).
- Feeling faint (especially when standing up).
- Problems with your sight for a short time.
- Stomach irritation.
- Diarrhoea or constipation.
- Allergic reactions.
- Fever
- Weakness
- Muscle cramps and muscle weakness.
- An increase in the amount of uric acid in your blood.
- Altered levels of substances in your blood (for example low sodium and potassium). You may notice muscle weakness, thirst, ‘pins and needles’, cramps or feeling sick.
- Raised or high levels of fats in your blood (including cholesterol).
- Changes to your vision that can make things look yellow.
- Severe eye pain with redness and sudden blurred vision. If you have a suddenly painful red eye tell your doctor immediately; you may need treatment to avoid permanent loss of vision.
- Damage to blood vessels causing red or purple spots in the skin.
- Difficulty breathing. You may feel breathless if your lungs get inflamed or have fluid on them.
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Yellowing of your skin or the whites of your eyes (jaundice).
- Skin problems including rash caused by sensitivity to sunlight, rash, severe rash that develops quickly with blistering or peeling of the skin and possibly blistering in the mouth, activating or worsening of existing lupus conditions or appearance of unusual skin reactions.
- Kidney problems which may be severe (shown in blood tests).

- 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)

Do not be concerned by this list of possible side effects. You may not get any of them.

#### 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 the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 Lisinopril and Hydrochlorothiazide Tablets

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Do not throw away any medicines via waste water or house hold 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 and Hydrochlorothiazide tablets contain**

- The active substances are Lisinopril (as dihydrate) and Hydrochlorothiazide.
- Lisinopril and Hydrochlorothiazide tablets come in two strengths, 10 mg/12.5 mg and 20 mg/12.5 mg. Each tablet contains either 10 mg of lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide or 20 mg lisinopril (as dihydrate) and 12.5 mg of hydrochlorothiazide.

The other ingredients of the tablets are: calcium hydrogen phosphate, mannitol, maize starch, pregelatinised starch and magnesium stearate. Lisinopril and Hydrochlorothiazide 10 mg/12.5 mg tablets also contain ferric oxide red (E172) and ferric oxide yellow (E172).

**What Lisinopril and Hydrochlorothiazide tablets looks like and contents of the pack**

- Lisinopril and Hydrochlorothiazide 10 mg/12.5 mg tablets are light pink, circular, biconvex mottled uncoated tablets.
- Lisinopril and Hydrochlorothiazide 20 mg/12.5 mg tablets are white to off white, circular, biconvex uncoated tablets.
- Lisinopril and Hydrochlorothiazide tablets come in packs containing 28 tablets.

**Marketing Authorisation Holder and Manufacturer**

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**Lisinopril and Hydrochlorothiazide 10 mg/12.5 mg tablets; PL 17907/0073**

**Lisinopril and Hydrochlorothiazide 20 mg/12.5 mg tablets; PL 17907/0074**

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