

LISDENE TABLET

Lisinopril dihydrate (5mg, 10mg & 20mg)

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What LISDENE is used for

Lisinopril is used to treat:

- high blood pressure
- reduced heart pumping ability (heart failure)
- patients recovering from a heart attack
- kidney disease resulting from diabetes and high blood pressure.

How LISDENE works

Lisinopril belongs to the ACE inhibitor medicine group (angiotensin-converting enzyme inhibitors). Lisinopril expands your blood vessels. This reduces your blood pressure and makes it easier for your heart to pump blood to all body parts

Before you take LISDENE

When you must not use it

Do NOT take LISDENE

- if you are allergic (hypersensitive) to
 - lisinopril or,
 - any of the other ingredients
 or,
 - other ACE inhibitors.
- if during earlier ACE inhibitor use you had swelling of the face, lips, tongue and/or throat with difficulty swallowing, breathing or with joints.
- If you have fluid accumulation (angioedema)
- if you are more than 3 months pregnant. (It is also better to avoid LISDENE in early pregnancy.

Before you start to use it

Tell your doctor if you have or have

had any medical condition especially the following:

- Dehydration due to treatment with water tablets (diuretics), dialysis, a low salt diet, vomiting or diarrhoea. If this applies to you, on starting medication you may frequently have a large drop in blood pressure.
- If you suffer from heart disorders such as heart failure, narrowing of the heart valves (aortic or mitral stenosis), or an increase in the thickness of the heart muscle (hypertrophic cardiomyopathy or 'HOCM') or if you have a condition involving the blood vessels in the brain.
- kidney problems
- If you are having dialysis, blood separation treatment to remove cholesterol from your blood or desensitisation treatment. In this cases, your doctor may interrupt your Lisinopril treatment to prevent an allergic reaction called anaphylaxis.
- blood vessel disease, known as collagen vascular disease

Pregnancy and breast-feeding

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 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lisinopril. Lisinopril 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.

Lactation

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

Taking other medicines

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

This particularly applies to:

- Diuretics ("water tablets") which are used to treat high blood pressure including potassium-sparing diuretics such as spironolactone, triamterence or amiloride.
- Other medicines used to treat high blood pressure.
- Medicines to treat arthritis or muscle pain, such as acetylsalicylic acid doses over 3 grams daily or indomethacin
- Medicines for mental disorders or depressions such as
 - Lithium
 - Medicines to treat psychoses
 - Tricyclic antidepressants, such as amitriptyline
- Potassium containing supplements or salt substitutes.
- Blood sugar lowering medicines, such as insulin or those taken orally. The antidiabetic medicine dose may need adjusting.
- Central nervous system stimulative medicines, such as
 - ephedrine or pseudoephedrine, which could be included in decongestants or

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- cough/cold remedies or
 - salbutamol, a medicine for treating asthma.
- Medicines to suppress the body's immune system
- Allopurinol, a medicines to treat gout
- Procainamide, used to treat abnormal heartbeats
- Gold injections (sodium aurothiomalate), a medicine to injection against rheumatic arthritis

How to take LISDENE

How much to take

The usual dose is:

• **For high blood pressure**

The recommended starting dose is 10mg.

For some conditions your doctor may decide to start you on between 2.5 mg-5mg.

Once optimal control of blood pressure has been reached, the usual effective maintenance dose is 20mg as a single daily dose.

If within a period of 2–4 weeks your blood pressure is not under control, your doctor may increase your dose further up to maximum of 80mg daily.

Diuretic-Treated Patients

If possible, the diuretic should be discontinued 2 to 3 days before beginning therapy with lisinopril. Patients with high blood pressure who cannot discontinue the diuretic therapy, should begin Lisinopril treatment with 5mg.

• **Heart conditions such as heart failure**

The usual starting dose is 2.5mg once a day. Your doctor may increase this dose if required at intervals of 2 weeks or more and by increments of 10mg or less.

• **Following a heart attack**

The usual dose is 5mg on Day 1 and Day 2, then 10mg taken once a day after your condition is stable following a heart

attack.

• **Diabetic patients with kidney problems**

The usual dose is 10mg once a day which may be increased by your doctor to 20mg once a day. If you suffer from a kidney disorder, the doctor should prescribe the lowest possible dose and monitor your kidney function.

• **Children**

The use of Lisinopril is not recommended.

• **Elderly, over 65 years**

No special dosage adjustment is necessary. In case of reduced kidney function the dose should be adjusted carefully.

• **Patients following recent kidney transplant**

The use of Lisinopril tablets is not recommended.

When to take it

Your medicine can be used before or after food and drinks. You should take your medicine at the same time each day with a drink of water

How long to take it

Do not stop treatment before talking to your doctor, as this will reduce the treatments effect

If you forget to take LISDENE

Take the missed dose as soon as you remember but never take two doses in one day.

If you use too much (overdose)

Contact your doctor or the nearest hospital casualty department immediately.

Take this leaflet or some tablets with you so that people will know what you have taken.

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

While you are using it

Things you must do

Inform your doctor:

- If you develop jaundice during use of Lisinopril, stop taking it and consult your doctor.
- If you need to have surgery or an anaesthetic, remind your doctor or dentist that you are taking Lisinopril.
- If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately

Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give LISDENE to anyone else, even if they have the same symptoms are condition as you.
- Do not stop taking the medicine unless advised by your doctor.

Things to be careful of

- Black people of Afro Caribbean origin have a higher risk of having:
 - sudden fluid accumulation in the skin and mucous membranes such as throat or tongue
 - breathing difficulties
 - itching and rash, often as an allergic reaction
 - a reduction of Lisinopril's effect

Driving and using machines

Dizziness or tiredness may occur when using Lisinopril. Do not drive or operate machinery if this affects you.

Side effects

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

Allergic reaction signs and symptoms are:

- difficulties in breathing.
- swelling of the face, hands, feets, lips, tongue and/or throat
- severe skin itch with raised lumps.

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Stop taking Lisinopril and seek medical advice immediately, if you develop any of the allergic reaction signs.

Side effects can occur with the following frequencies:

Common, occurs in 1 to 10 per 100 users:

- dizziness
- headache
- fall in blood pressure as a result e.g. of standing up rapidly from a sitting or lying position sometimes accompanied by dizziness
- cough
- diarrhoea
- vomiting
- kidney problems

Uncommon, occurs in 1 to 10 per 1000 users:

- mood changes
- the sensation of pins and needles
- vertigo
- taste abnormalities
- difficulty in sleeping
- possible heart attack or stroke in high risk patients
- increased heart rate
- heart palpitations
- numbness or tingling in the fingers and toes
- runny nose
- feeling sick (nausea)
- abdominal pain
- indigestion
- skin rash and/or itching
- sudden accumulation of fluid in the skin and mucous membranes (e.g. throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (hypersensitivity/ angioneurotic oedema)
- inability to maintain an erection (impotence)
- tiredness
- general weakness
- increase in blood urea, serum creatinin or liver enzyme values
- too much potassium in the blood, sometimes manifesting itself as muscle cramps,

diarrhoea, nausea, dizziness, headache (hyperkalaemia)

Rare, occurs in 1 to 10 per 1000 users:

- decrease of the red blood pigment haemoglobin and number of red blood cells (haematocrit)
- mental confusion
- dry mouth
- nettle rash
- hair loss
- psoriasis, a skin disorder
- kidney failure leading to excessive urea in the blood
- enlargement of one or both breasts in men or non-breast feeding women
- increase of bilirubin, a substance produced in the liver
- low sodium level in the blood (signs are tiredness, confusion and muscle twitching)

Very rare, occurs in less than 1 of 10 000 users:

- inhibition of the formation of blood in the bone marrow
- deficiency of red blood cells with signs such as looking pale or feeling tired
- unexpected bruising
- blood abnormality and abnormalities of the lymph glands
- low blood sugar levels
- difficulty in breathing, inflammation of nasal sinuses, certain forms of pneumonia
- inflammation of the pancreas
- allergic reaction in the small intestine (intestinal angioedema)
- inflammation of the liver (hepatitis) or other liver disorders such as jaundice (yellowing of the skin and/or the whites of the eyes)
- severe skin disorders including Stevens-Johnson Syndrome and aggregate of mature or abnormal looking lymphocytes in the dermis (cutaneous pseudolymphoma)
- excessive sweating (diaphoresis)

- production of less urine and/or passing urine less frequently.

Frequency unknown:

depressive symptoms, syncope

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the **National Centre for Adverse Drug Reaction Monitoring** by calling Tel: **03-78835550**, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of LISDENE

Storage

Keep out of the reach and sight of children.

Do not use LISDENE after the expiry date "EXP" which is stated on the packaging. The expiry date refers to the last day of that month.

Blister: Keep the blister in the outer carton in order to protect from light.

Disposal

Medicinal should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

Product Description

LISDENE 5mg tablets

What it looks like

All the 3 strengths of LISDENE is a round, convex slightly red tablet with a score notch on one side.

Ingredients

Active ingredients

One tablet LISDENE 5 mg contains 5.44 mg lisinopril dihydrate, equivalent to 5 mg lisinopril.

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One tablet LISDENE 10 mg contains 10.89 mg lisinopril dihydrate, equivalent to 10 mg lisinopril.

One tablet contains 21.78 mg lisinopril dihydrate, equivalent to 20 mg lisinopril.

Inactive ingredients

The other ingredients for all the 3 strengths of LISDENE are calcium hydrogen phosphate dihydrate, mannitol, maize starch, croscarmellose sodium and magnesium stearate & ferric oxide red.

MAL NO.

Lisdene 5mg- MAL09122787A

Lisdene 10mg- MAL10021808AS

Lisdene 20mg- MAL09122788A

Manufacturer

Lek Pharmaceuticals d.d

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Product registration holder

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