

LISINOPRIL STADA® 10MG TABLET

Lisinopril 10.89mg (equivalent to 10mg lisinopril)

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What Lisinopril STADA® 10 mg is used for

- Treatment of high blood pressure (arterial hypertension)
- Treatment of symptomatic heart failure (cardiac insufficiency)
- Acute heart attack (acute myocardial Infarction) – of patients with a stable cardiocirculatory situation (haemodynamically stable patients with a systolic blood pressure above 100mmHg, serum-creatinine below 177µmol/l (2.0mg/dl) and proteinuria less than 500mg/24hours. Lisinopril should be administered additionally to the usual standard heart attack treatment, preferably together with nitrates.

How Lisinopril STADA® 10 mg works

- Lisinopril STADA® 10 mg is an angiotensin-converting enzyme inhibitor (ACE inhibitor) for the treatment of high blood pressure.

Before you take Lisinopril STADA® 10 mg

When you must not take it

- If you are allergic (hypersensitive) to lisinopril or any of the other ingredients of Lisinopril STADA® 10 mg or to another angiotensin converting enzyme (ACE) inhibitor
- if you have had a tissue swelling (angioneurotic edema) related to

previous treatment with an ACE inhibitor

- if you are suffering from an inherited or idiopathic (without identifiable cause) angioedema (serious allergic reaction which causes swelling of the face or throat)
- In the second and third trimester of pregnancy.

Before you start to take it

- Always take Lisinopril STADA® 10 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- It is recommended to initiate lisinopril-therapy under hospital conditions for patients:
 - Undergoing a combined and highly dose therapy with diuretics (eg. More than 80mg furosemide)
 - With fluid or salt deficit (hypovolemia or hyponatremia: serum sodium less than 130mmol/l)
 - With pre-existing hypotension
 - With instable cardiac insufficiency
 - With reduced kidney function
 - Undergoing highly dosed therapy with vasodilators
 - 70 years or older

Taking other medicine

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. For example:
 - Diuretics
 - Potassium supplements, potassium-sparing diuretics (certain water tablets)
 - Lithium (medicine for psychic disorders and depression)
 - Painkillers for inflammatory conditions (Non steroidal anti

inflammatory drugs eg. Aspirin, indomethacin)

- Other blood pressure reducing (antihypertensive) agents
- Sympathomimetics (medicines with stimulating effects)
- Antidiabetics (blood sugar reducing drugs)
- Sodium chloride (salt)
- Allopurinol
- Medication that suppresses the defense reaction (cytostatics, immunosuppressives, systemic corticoids)
- Procainamide
- Antacids

How to take Lisinopril STADA® 10 mg

How much to take

- Starting dose
 - In patients with hypertension the usual recommended starting dose is ½ tablet Lisinopril STADA® 10 mg (equivalent to 5 mg lisinopril). A lower starting dose, ¼ tablet Lisinopril STADA® 10 mg once daily in the morning (equivalent to 2.5mg lisinopril/day) is required in the presence of renal impairment.
- Maintenance dose
 - The usual effective maintenance dosage is 1-2 tablets Lisinopril STADA® 10 mg (equivalent to 10-20 mg lisinopril) taken in a single daily dose. The maintenance dose in moderately reduced renal function is usually ½ -1 tablets Lisinopril STADA® 10 mg daily (equivalent of 5-10mg lisinopril/day). The maximum dose of 20mg lisinopril per day should not be exceeded.

When to take it

- Lisinopril STADA® 10 mg should be taken once a day in the morning.

How long to take it

- Do not interrupt or stop treatment with Lisinopril STADA® 10mg before consulting your doctor. If you have any further questions on

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the use of this product, ask your doctor or pharmacist.

If you forget to take it

- Do not take a double dose to make up for a forgotten tablet.

If you take too much (overdose)

- Limited data are available for overdose in humans. Symptoms associated with overdosage of ACE inhibitors may include hypotension, circulatory shock, electrolyte disturbances, renal failure, slowed heart rate (bradycardia). Contact your physician immediately upon overdose to determine the severity and initiate the necessary measures.

While you are using Lisinopril STADA® 10 mg

Things you must do

- Always take Lisinopril STADA® 10 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- When pregnancy is planned or confirmed the switch to an alternative treatment should be initiated as soon as possible.

Things you must not do

- The use of Lisinopril STADA® 10 mg is not recommended in women who are breast-feeding and children
- Lisinopril STADA® 10 mg should not be used during the first trimester of pregnancy.
- Lisinopril STADA® 10mg are contraindicated during the second and third trimester of pregnancy.
- Do not use Lisinopril STADA® 10 mg after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

Things to be careful of

- When driving vehicles or operating machines it should be taken into

account that occasionally dizziness or tiredness may occur.

- When pregnancy is planned or confirmed the switch to an alternative treatment should be initiated as soon as possible.

Side effects

- Common side effects are fever, inflammation of blood vessels, often with skin rash, muscle pain (myalgia), joint pain (arthralgia/arthritis), changes in laboratory values, rash, dizziness, cough, diarrhea, vomiting, impaired kidney function, weakness, impaired vision, loss of consciousness, sore throat, hoarseness, bronchitis, nausea, abdominal pain, indigestion and excessive drop of blood pressure.
- 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 visiting the website nptra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Lisinopril STADA® 10 mg

Storage

- Keep out of the reach and sight of children.
- Do not store above 30°C.

Disposal

- Medicines 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

What it looks like

- Lisinopril STADA® 10 mg is white, round, biconvex tablet, quadrisected on both sides (snap-tab) and imprint "10".
- Lisinopril STADA® 10mg is packed in PVC/aluminium blisters containing 100 tablets per pack.

Ingredients

- Active ingredient:**
The active substance is lisinopril. 1 tablet contains 10.89mg lisinopril equivalent to 10mg lisinopril.
- Inactive ingredient:**
The other ingredients are Calcium hydrogen phosphate dehydrate, silica colloidal anhydrous, magnesium stearate, maize starch, mannitol, maize starch pregelatinised.

MAL number(s):

MAL20033968AZ

Manufacturer

Manufactured under the license of:
STADApHarm GmbH,
61118 Bad Vilbel, Germany
By: Stellapharm J.V. Co., Ltd.
Branch 1 No. 40 Tu Do Avenue
VietNam-Singapore Industrial Park,
An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam

Product Registration Holder

DKSH Malaysia Sdn Bhd,
B-11-01, The Ascent, Paradigm
No.1, Jalan SS7/26A, Kelana Jaya
47301 Petaling Jaya
Selangor Darul Ehsan

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