

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vitopril

Vitopril 5 mg tablets; Vitopril 10 mg tablets; Vitopril 20 mg tablets

LISINOPRIL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What VITOPRIL is and what it is used for
2. Before you take VITOPRIL
3. How to take use VITOPRIL
4. Possible side effects
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1. WHAT VITOPRIL IS AND WHAT IT IS USED FOR

VITOPRIL contains Lisinopril which belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme inhibitors). Lisinopril works by widening your blood vessels, which helps reduce your blood pressure and makes it easier for your heart to pump blood to all parts of your body.

VITOPRIL is used if:

- Your blood pressure is too high (hypertension).
- You have a heart condition known as symptomatic heart failure, where the heart does not pump your blood around your body as well as it should.
- You have had a heart attack (myocardial infarction) that may lead to a weakening of your heart. Lisinopril slows the weakening down.
- You have kidney problems related to your diabetes and high blood pressure.

2. BEFORE YOU TAKE VITOPRIL

Do not take VITOPRIL

- If you are allergic to Lisinopril or any of the other ingredients (listed in section 6).

- If you have previously been treated with a medicine in the same group of drugs as Lisinopril (ACE inhibitors) and have had an allergic reaction which caused swelling of the hands, feet, or ankles, the face, lips, tongue and/or throat with difficulty in swallowing or breathing or if you or a member of your family have had a similar reaction.
- If you are more than 3 month pregnant. (It is also better to avoid VITOPRIL tablets in early pregnancy• see pregnancy section).

Take special care with VITOPRIL

Talk to your doctor or pharmacist before taking VITOPRIL Tablets if you have or have had any medical condition, especially the following:

- You must tell your doctor if you think you are (or might become) pregnant. VITOPRIL tablet 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 section).

- Symptomatic hypotension (low blood pressure)

Rarely, Vitopril can cause low blood pressure (symptomatic hypotension), especially at the beginning of treatment.

It is more likely to happen in patients who have

- Low blood pressure (you may notice this as dizziness or light headedness especially when standing).
- Kidney disease or you are undergoing dialysis.
- Liver disease
- Blood vessel disease (collagen vascular disease) and/or treatment with allopurinol (for gout), procainamide (for abnormal heartbeats), immunosuppressants (medicines which suppress the body's immune response), diuretics and drugs which increase potassium levels (including heparin).
- Diarrhea or vomiting.
- A salt-restricted diet or you are taking potassium supplements.
- If you are taking any of the following medicines used to treat high blood pressure:
 - angiotensin II receptor blocker (ARBs) (also known as sartans • for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
 - aliskiren

Stop taking VITOPRIL and seek medical attention immediately if any of the following situations occur (an allergic reaction):

- If you develop difficulty in breathing with or without swelling of the face, lips, tongue and/or throat.
- If you develop swelling of the face, lips, tongue and/or throat which may cause difficulty in swallowing.
- If you develop severe itching of the skin (with raised lumps).

Tell your doctor if you are undergoing/or will undergo desensitisation treatment for an allergy, for example, to insect stings. The desensitisation treatment reduces the effects of the allergy (e.g. bee or wasp stings) but sometimes it can cause a more severe allergic reaction if you are taking ACE inhibitors during the desensitisation treatment.

Tell your doctor if you are going into hospital for an operation.

Tell your doctor or dentist that you are taking VITOPRIL before you are given a local or general anesthetic. VITOPRIL, combined with some anesthetics, may cause a short-term drop in blood pressure soon after taking the tablets.

Taking other medicines

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

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 VITOPRIL Tablets")".

Talk to your doctor if you are taking any of the following medicines:

- Diuretics (water tablets including those which conserve potassium).
- Other medicines for your high blood pressure (antihypertensives).
- Non-steroidal anti-inflammatory medicines (NSAIDs) such as Indometacin and high doses of aspirin (more than 3 grams per day), which are used to treat arthritis or muscle pain.
- Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.
- Medicines for mental disorders such as lithium, anti-psychotics or tricyclic antidepressants.
- Potassium tablets or potassium containing salt substitutes.
- Medicines for the treatment of diabetes, such as insulin or those taken orally, to lower blood sugar.
- Medicines that stimulate the central nervous system (sympathomimetics). These include ephedrine, pseudoephedrine and salbutamol and may be found in some decongestants, cough/cold remedies and asthma medication.
- Medicines that suppress the body's immune response (immunosuppressants), treatment with allupurinol (for gout) or procainamide (for abnormal heartbeats).

Taking food and drink with VITOPRIL

Food intake does not affect Vitopril, so it can be taken with or without food, but try to take it each day at the same time.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking VITOPRIL tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of VITOPRIL tablets. VITOPRIL tablets 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.

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breastfeeding. VITOPRIL tablets 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

Lisinopril may have a minor or moderate effect on ability to drive and use machines. If you experience side effects like dizziness or tiredness, you should not drive or operate machines.

3. HOW TO TAKE VITOPRIL

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Vitopril can be taken with or without meals. Swallow the tablet with enough liquid eg, one glass of water. Daily dose is generally administered once a day, at about the same time. Vitopril should be taken until your doctor prescribes it.

How much to take

Your doctor will tell you how many tablets to take each day. The dosage is individual and it is important that you take it as prescribed by your doctor. Your starting dose and long term dose will depend on your medical condition and whether you are taking any other medicines. Check with your doctor or pharmacist if you are unsure.

High blood pressure

Vitopril can be taken alone or with other medicines that lower blood pressure. The usual starting dose is 10 mg taken once a day. This dose is slowly increased in periods of 2-4 weeks until desired control of blood pressure is obtained. The usual dose is 20 mg taken once a day and, if necessary, it can be gradually increased up to 80 mg once a day.

If you are already taking medicines for urination, your doctor will ask you to stop taking them 2-3 days before taking Vitopril. If your treatment with diuretics cannot be stopped, treatment with Vitopril should start with a dose of 5 mg once a day. Further doses should be adjusted according to your response to the treatment. Treatment with diuretics can be continued again.

If you have kidney problems, you may need to start with a lower dose, and your doctor will decide on the dose depending on the severity of kidney problems and will monitor you closely, especially when starting therapy with Vitopril.

Use in children and adolescents aged 6 to 16 years

The dose depends on your weight. The usual starting dose is between 2.5mg and 5mg once daily, which can be increased to a maximum of 20mg to 40mg once daily. Patients with kidney problems should take a lower dose. Your doctor will decide the correct dose for you.

Symptomatic heart failure

Vitopril should be taken along with other therapy for the treatment of heart failure (for example, urination medicines, beta blockers, and digitalis).

The usual starting dose is 2.5 mg once a day, which should be taken under medical supervision. This dose is then increased gradually to a maximum of 10 mg in the interval of at least 2 weeks in order to monitor symptoms of heart failure.

Maximum daily dose is 35 mg to be taken once a day. Your doctor will decide the correct dose for you.

Acute heart attack

After taking the recommended standard therapy (eg, thrombolytics, beta-blockers), the usual starting dose

- is 5 mg within 24 hours after the infarction
- then 5 mg, 24 hours after taking the first dose
- then 10 mg, 48 hours after taking the first dose and in the following days 10 mg once daily.

The usual maintenance dose is 10 mg once daily.

Your doctor may reduce your dose if you have low blood pressure due to kidney disease.

The treatment should last for 6 weeks.

Problems related to diabetes

The usual starting dose is 10 mg once daily in patients with high blood pressure. This dose can be increased to 20 mg once daily if necessary.

If you have kidney problems the dose may be adjusted, if necessary.

Children

Vitopril should not be taken by children under 6 years of age or children with severe kidney problems. Ask your doctor for advice.

Elderly

Elderly patients with normal renal function may take the usual recommended dose.

Patients with kidney transplant

Vitopril should not be taken by patients who have a kidney transplant.

If you take more VITOPRIL than you should

Contact your doctor or nearest hospital immediately if you have taken more than you should.

Symptoms of overdose include low blood pressure, circulatory shock, disorders of electrolyte balance (such as low levels of potassium, sodium and chloride in the blood), renal failure, rapid breathing (hyperventilation), rapid heart rate (tachycardia), irregular heartbeat (palpitations), slow heart rate (bradycardia), dizziness, anxiety (exaggerated sense of fear and tension) and cough.

If you forget to take VITOPRIL

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

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

If you stop taking VITOPRIL

Do not interrupt or completely stop taking Vitopril before consulting your doctor.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

According to the frequency, side effects are divided into:

Very common (more than 1 in 10 patients),

common (less than 1 in 10 patients),

uncommon (less than 1 in 100 patients),

rare (less than 1 in 1000 patients),

very rare (less than 1 in 10,000 patients).

After taking the first one or two doses you can experience dizziness or loss of consciousness due to a decrease in blood pressure. This usually stops if you lie down.

You should stop taking Vitopril and immediately inform your doctor if you:

- Feel itchiness or get a serious skin reaction
- Experience wheezing during breathing, difficulty breathing or swallowing
- Notice swelling of the hands, feet or ankles, face, lips, tongue or throat, or you notice yellowing of the skin or whites of the eyes (jaundice)

Other side effects:

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

Headache

Dizziness or light-headedness especially when standing up quickly

Diarrhea

Cough

Vomiting

Lisinopril may affect the kidneys, causing abnormally low or no urine to be passed.

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

Mood changes

Change of color (pale blue followed by redness) and/or numbness or tingling in the fingers or toes

Changes in the way things taste

Feeling sleepy or difficulty in going to sleep, strange dreams

Rapid heartbeat

Running nose

Nausea

Stomach pain or indigestion

Skin rash

Itching

Impotence

Tiredness

Weakness (loss of strength).

An excessive drop in blood pressure may be experienced in patients with coronary heart disease, or those with a narrowing of the aorta (aortic stenosis), the kidney artery (renal artery stenosis) or the heart valves (mitral valve stenosis), or those patients with an increase in the thickness of the heart muscle (hypertrophic cardiomyopathy).

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

Rarely, there may be changes to some of the cells or other parts of your blood. It is possible that your doctor may occasionally take blood samples to check whether Lisinopril has had any effect on your blood. Sometimes these changes may show themselves as tiredness or a sore throat, or they may be accompanied by a fever, joint and muscle pains, swelling of the joints or glands, or sensitivity to sunlight.

Other rare side effects are:

Confusion

Dry mouth

Hair loss

Skin rash

Psoriasis

Development of breasts in men.

Low levels of sodium in your blood (the symptoms may be tiredness, headache, nausea, vomiting)

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

Sinus pain

Wheezing

Inflammation of the lungs

Yellow skin and/or eyes (jaundice)

Inflammation of the liver or pancreas

Severe skin disorders (symptoms of which include redness, blistering and peeling)

Sweating.

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

Symptoms of depression

Fainting

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.

5. HOW TO STORE VITOPRIL

Keep out of the reach and sight of children.

Do not store above 30 °C.

Return any unused Lisinopril tablets to your pharmacist.

Do not use VITOPRIL after the expiry date which is stated on the label.

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. FURTHER INFORMATION

What VITOPRIL contains

The active substance is lisinopril (as hydrate).

One tablet contains 5 mg, 10 mg or 20 mg of lisinopril.

The other ingredients are: calcium hydrogen phosphate dihydrate; silica, colloidal anhydrous; magnesium stearate; corn starch; mannitol (E421); starch, pregelatinised.

What VITOPRIL looks like and contents of the pack

Vitopril 5 mg are white, round, biconvex tablets imprinted with the label '5' on one side and score line on both sides. Each tablet contains 5.44 mg of lisinopril dihydrate which corresponds to 5 mg of lisinopril.

Vitopril 10 mg tablets are white, round, biconvex with imprinted label '10' on one side and a double score line on both sides. Each tablet contains 10.89 mg of lisinopril dihydrate, which corresponds to 10 mg of lisinopril.

Vitopril 20 mg tablets are white, round, biconvex with imprinted label '20' on one side and score line on both sides. Each tablet contains 21.78 mg of lisinopril dihydrate which corresponds to 20 mg of lisinopril.

Vitopril tablets are available in a package with 30 tablets and 60 tablets.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Stada Arzneimittel AG
Stada Strasse 2-18, Bad Vilbel
Germany

Manufacturer of the medicinal product

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Stada Strasse 2-18, Bad Vilbel
Germany