

Package leaflet: Information for the patient

COVERSYL® 8 mg

Perindopril tert-butylamine

کوریسل®
بیئرٹڈوپریل ٲرٹربوٹائل مین
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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 of the 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 COVERSYL 8 mg, tablet is and what it is used for
2. What you need to know before you take COVERSYL 8 mg, tablet
3. How to take COVERSYL 8 mg, tablet
4. Possible side effects
5. How to store COVERSYL 8 mg, tablet
6. Contents of the pack and other information

1. WHAT COVERSYL 8 mg, tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: ACE inhibitors, plain - ATC code: C09AA04
COVERSYL 8 mg, tablet is an angiotensin converting enzyme (ACE) inhibitor. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them.

COVERSYL 8 mg, tablet is used:

- To treat high blood pressure (hypertension),
- To reduce the risk of cardiac events, such as heart attack, in patients with stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) and who have already had a heart attack and/or bypass surgery or a procedure to dilate the coronary arteries.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE COVERSYL 8 mg, tablet

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Do not take COVERSYL 8 mg, tablet:

- if you are allergic (hypersensitive) to perindopril or any of the ingredients of this medicine (listed in section 6), or to any other ACE inhibitor,
- if you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema),
- if you are more than 3 months pregnant (it is also preferable to avoid taking COVERSYL 8 mg, tablet in early pregnancy – see Pregnancy and Breast-feeding sections),
- if you have diabetes or impaired kidney function and you are being treated with a blood pressure lowering medicine containing aliskiren,
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, COVERSYL may not be suitable for you,
- if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis),
- if you are being treated with sacubitril/valsartan, a medicine for heart failure (see "Warning and Precaution" and "Other medicines and COVERSYL 8 mg, tablets").

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking COVERSYL 8 mg, tablet, if you:

- have aortic stenosis (narrowing of the main artery leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the renal artery),
- have any other heart problems,
- have liver problems,
- have kidney problems or if you are receiving dialysis,
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- suffer from a collagen vascular disease (disease of the connective tissue), such as systemic lupus erythematosus or scleroderma,
- have diabetes,
- are on a salt-restricted diet or use salt substitutes which contain potassium,
- are going to have an anaesthetic and/or major surgery,
- are to undergo LDL apheresis (which is removal of cholesterol from your blood by a machine),
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- have recently suffered from diarrhoea or vomiting, or are dehydrated, have an intolerance to some sugars,
- are taking any of the following medicines used to treat high blood pressure:
 - an "angiotensin II receptor blocker" (ARB) (also known as a sartan - for example, valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems,
 - aliskiren.
 - 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 COVERSYL 8 mg, tablet".

- are of black origin: this medicine may increase your risk of angioedema and be less effective in lowering your blood pressure than in non-black patients.
- are taking any of the following medicines, the risk of angioedema is increased:
 - rabeprazole (used to treat diarrhoea),
 - sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors (used to avoid rejection of transplanted organs),
 - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.

Angioedema

Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat which makes swallowing or breathing difficult) has been reported in patients treated with ACE inhibitors, including COVERSYL 8 mg, tablet. This may occur at any time during treatment. If you develop such symptoms, stop taking COVERSYL 8 mg, tablet at once and see a doctor immediately (see section 4).

You must tell your doctor if you think that you are (or might become) pregnant. COVERSYL 8 mg, 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 and Breast-feeding section).

Due to the presence of lactose, patients with rare hereditary problems of galactose intolerance, glucose-galactose malabsorption, or the Lapp lactase deficiency should not take this medicinal product.

Children and adolescents

The use of perindopril in children and adolescents under the age of 18 years is not recommended.

Other medicines and COVERSYL 8 mg, tablet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Treatment with COVERSYL 8 mg, tablet can be affected by other medicines. Your doctor may need to change the doses of your medications and/or take other precautions if you are taking any of the following:

- other medicines for high blood pressure, including angiotensin II receptor blockers (ARBs), aliskiren (see also information under the headings "Do not take COVERSYL 8 mg, tablet" and "Warnings and precautions") or diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing diuretics (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes, other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole),
- potassium-sparing diuretics used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg and 50 mg per day,
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high doses of aspirin,
- medicines used in the treatment of diabetes (such as insulin or metformin),
- baclofen (used to treat muscle stiffness associated with diseases such as multiple sclerosis),
- medicines used in the treatment of mental disorders, such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, antipsychotics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used in the treatment of auto-immune disorders or following transplant surgery (cyclosporin, tacrolimus),
- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- medicines, which are most often used to treat diarrhoea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTOR inhibitors). See section "Warnings and precautions",
- sacubitril/valsartan (used to treat long-term heart failure). See sections "Do not take COVERSYL 8 mg, tablets" and "Warnings and precautions",
- procainamide (for the treatment of an irregular heartbeat),
- allopurinol (for the treatment of gout),
- vasodilators, including nitrates (products that make the blood vessels become wider),
- medicines used for the treatment of low blood pressure, shock or asthma (ephedrine, noradrenaline or adrenaline),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

COVERSYL 8 mg, tablet with food and drink

It is preferable to take COVERSYL 8 mg, tablet before a meal.

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 Coversyl 8 mg, tablet before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Coversyl 8 mg, tablet. COVERSYL 8 mg, tablet 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 breast-feeding. COVERSYL 8 mg, tablet 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. Ask your doctor or pharmacist for advice before taking any medicine. Athletes Not applicable.

Driving and using machines

COVERSYL 8 mg, tablet usually does not affect alertness but dizziness or weakness due to low blood pressure may occur in certain patients. If you are affected in this way, your ability to drive or to operate machinery may be impaired.

COVERSYL 8 mg, tablet contains lactose

If you have been told by your doctor that you have an intolerance to some

Package leaflet: Information for the patient

sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE COVERSYL 8 mg, tablet

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

Swallow your tablet with a glass of water, preferably at the same time each day, in the morning and before a meal. Your doctor will decide on the correct dose for you.

The usual doses are as follows:

High blood pressure: the usual starting and maintenance dose is 4 mg once daily. After one month, this dose can be increased to 8 mg per day, if required. 8 mg per day is the maximum recommended dose for high blood pressure.

If you are over the age of 65, the usual starting dose is 2 mg per day. After one month, this can be increased to 4 mg per day and then, if necessary, to 8 mg per day.

Stable coronary artery disease: the usual starting dose is 4 mg per day. After two weeks, this can be increased to 8 mg per day, which is the maximum recommended dose in this indication.

If you are over the age of 65, the usual starting dose is 2 mg per day. After one week, this can be increased to 4 mg per day and after a further week to 8 mg per day.

If you take more COVERSYL 8 mg, tablet than you should:

Contact your nearest accident and emergency department or tell your doctor or pharmacist immediately.

The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness), lying down with the legs raised can help.

If you forget to take COVERSYL 8 mg, tablet:

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of COVERSYL 8 mg, tablet, take the next dose at the usual time.

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

If you stop taking COVERSYL 8 mg, tablet:

As the treatment with COVERSYL 8 mg, tablet is usually life-long, you should discuss with your doctor before stopping this medicinal product.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking COVERSYL 8 mg, tablet at once and see a doctor immediately, if you experience any of the following potentially serious side effects:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (see section 2 "Warnings and precautions") (uncommon - may affect up to 1 in 100 patients),
- severe dizziness or fainting due to low blood pressure (common - may affect up to 1 in 10 patients),
- unusually fast or irregular heartbeat, chest pain (angina) or heart attack (very rare - may affect up to 1 in 10,000 patients),
- weakness of the arms or legs, or problems in speaking, which could be signs of a possible stroke (very rare - may affect up to 1 in 10,000 patients),
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (uncommon - may affect up to 1 in 100 patients),
- inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling very unwell (very rare - may affect up to 1 in 10,000 patients),
- yellowing of the skin or eyes (jaundice), which could be a sign of hepatitis (very rare - may affect up to 1 in 10,000 patients),
- skin rash, which often starts with red itchy patches on the face, arms or legs (erythema multiforme) (very rare - may affect up to 1 in 10,000 patients).

Tell your doctor if you notice any of the following side effects:

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

- headache,
- dizziness,
- vertigo,
- pins and needles,
- vision disturbances,
- tinnitus (sensation of noises in the ears),
- cough,
- shortness of breath (dyspnoea),
- gastrointestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficult digestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- muscle cramps,
- feeling of weakness.

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

- mood swings,
- sleep disturbances,
- dry mouth,
- intense itching or severe skin rashes,
- formation of blister clusters over the skin,
- kidney problems,
- impotence,
- sweating,
- excess eosinophils (a type of white blood cells),
- somnolence,
- fainting,
- palpitations,
- tachycardia,
- vasculitis (inflammation of blood vessels),
- photosensitivity reaction (increased sensitivity of the skin to sun),
- arthralgia (joint pain),
- myalgia (muscle pain),
- chest pain,
- malaise,
- oedema peripheral,
- fever,
- fall,

changes in laboratory parameters: increased blood potassium levels reversible on treatment discontinuation, decreased sodium levels, hypoglycaemia (very low blood sugar levels) in diabetic patients, increased blood urea levels and increased blood creatinine levels.

Rare (may affect up to 1 in 1000 patients):

- psoriasis worsening

- changes in laboratory parameters: increased liver enzymes levels, high serum bilirubin levels.

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

- confusion,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- acute renal failure,
- changes in blood values, such as reduced numbers of white and red blood cells, a reduction in haemoglobin, a reduced number of blood platelets.

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor as soon as possible.

Unknown frequency (cannot be estimated from the available data):

- discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon).

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 to drug regulatory authority of Pakistan via www.dra.gov.pk or to company website www.servier.com.pk.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE COVERSYL 8 mg, tablet

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

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 COVERSYL 8 mg, tablet contains

The active substance is: Perindopril..... 6.676 mg

In the form of perindopril tert-butylamine 8.000 mg

For one tablet

- The other ingredients are:

Aluminium copper complexes of chlorophyllins lake (E411 ii), microcrystalline cellulose, lactose monohydrate, hydrophobic colloidal silica, magnesium stearate.

What COVERSYL 8 mg, tablet looks like and contents of the pack

This medicine is presented in the form of green, round, biconvex tablets, with engraved on one face and on the other face, in boxes of 10 tablets.

Marketing Authorisation Holder and Manufacturer

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