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What is Coversyl 4 mg:
Coversyl 4 mg is an angiotensin converting enzyme (ACE) inhibitor. It works by widening the blood vessels, which makes it easier for your heart to pump blood to your body.

What is angioedema:
Angioedema is a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing.

What are the warnings and precautions of Coversyl 4 mg:

1. What Coversyl 4 mg is and what it is used for
Coversyl 4 mg is used:
- to treat high blood pressure (hypertension),
- to treat heart failure (a condition where the heart is unable to pump enough blood to meet the body’s needs),
- to reduce the risk of certain heart 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 an operation to improve the blood supply to the heart by widening the vessels that supply it.

Before you take Coversyl 4 mg
Do not take Coversyl 4 mg:
- if you are allergic to perindopril, or any of the other ingredients of this medicine (listed in Section 6), or to any other ACE inhibitor.
- if you have experienced symptoms such as swelling, 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 better to avoid Coversyl 4 mg in early pregnancy – see pregnancy section).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you are having dialysis or any other type of blood filtration.
- if you are allergic to perindopril, or any of the other ingredients of this medicine (listed in Section 6), or to any other ACE inhibitor.
- 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 Perindopril Arrow Generiques”).

Warnings and precautions
If any of the following apply to you please talk to your doctor or pharmacist before taking Coversyl 4 mg:
- If you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the blood supply to the kidney).
- if you are affected by diabetes.
- if you have any other heart problems.
- if you have liver problems.
- if you have kidney problems if you are receiving dialysis.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have dental surgery or any other type of blood filtration.
- if you are allergic to perindopril, or any of the other ingredients of this medicine (listed in Section 6), or to any other ACE inhibitor.
- if you have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the blood supply to the kidney).
- if you have diabetes.
- if you are on a salt restricted diet or use salt substitutes which contain phosphates.
- if you are going to have a general anaesthetic and/or major surgery.
- if you are under 18, apnoea (which is a problem of breathing) or have a sleep apnoea syndrome.
- if you have recently suffered from diarrhea or vomiting, or are dehydrated.
- if you breast-feed.
- if you are taking any of the following medicines used to treat high blood pressure:
- an “angiotensin II receptor blocker” (ARB) also known as sartans for example valsartan, telmisartan, irbesartan, in particular if you have diabetes-related kidney problems.
- allopurinol.
- your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Special information under the heading “Concomitant Coversyl 4 mg”:
- if you are black or sickle cell anaemia patients you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients.
- if you are taking any of the following medicines, the risk of angioedema is increased:
  - ACE inhibitors (used to treat diabetes)
  - 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.

Other medicines and Coversyl 4 mg
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Blood pressure lowering medicines:
There are many different types of blood pressure lowering medicines, each of which work in different ways. All work to lower blood pressure and may cause certain side effects.

- “ACE inhibitors” are drugs used to treat high blood pressure. They do this by lowering blood pressure (which reduces the workload on the heart).
- “Diuretics” (water pills) are used to decrease the amount of water in your body.
- “Vasodilators” are drugs which widen the blood vessels which supply blood to the heart.
- “Beta blockers” block the affects of adrenaline on the heart and other organs of the body so reducing heart rate and blood pressure.
- “Calcium channel blockers” block the effects of calcium on muscle cells, so reducing heart rate and blood pressure.
- “Potassium-sparing drugs” are used in heart failure to increase potassium in your body.

Combining these types of medicine may cause certain side effects, such as dizziness and fainting.

Driving and using machines:
Some medicines can affect your ability to drive or to operate machines.

Coversyl 4 mg 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 machines may be impaired.

Coversyl 4 mg contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

How to take Coversyl 4 mg
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Pack and keep out of the reach of children.

The recommended dosages are as follows: 4 mg/day.
Package leaflet: Information for the patient

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

If you are 65 or older, the usual starting dose is 2 mg once a day. After a month this can be increased to 4 mg once a day and then if necessary to 8 mg once daily.

Heart failure: the usual starting dose is 8 mg once daily. After two weeks, this can be increased to 4 mg once a day, which is the maximum recommended dose for heart failure.

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

If you are 65 or older, the usual starting dose is 2 mg once a day. After a week this can be increased to 4 mg once a day and after a further week to 8 mg once daily.

Use in children and adolescent

Use in children and adolescent is not recommended.

If you take more Coversyl 4 mg than you should

If you take too many tablets, contact your nearest accident and emergency department or tell your doctor immediately. The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint. If this happens, lying down with the legs raised can help.

If you forget to take Coversyl 4 mg

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Coversyl 4 mg, 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 4 mg

As the treatment with Coversyl 4 mg 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 the medicinal product and see a doctor immediately, if you experience any of the following side effects that can be serious:

- 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 people),
- severe dizziness or fainting due to low blood pressure (Common - may affect up to 1 in 10 people),
- unusual fast or irregular heartbeat, chest pain (angina) or heart attack (Very rare - may affect up to 1 in 10,000 people),
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke (Very rare - may affect up to 1 in 10,000 people),
- sudden wheeze, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (Uncommon - may affect up to 1 in 10 people),
- 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 people),
- yellowing of the skin or eyes (jaundice) which could be a sign of hepatitis (Very rare - may affect up to 1 in 10,000 people),
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme) (Very rare - may affect up to 1 in 10,000 people).

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

Common (may affect up to 1 in 10 people):
- headache,
- dizziness,
- vertigo,
- pins and needles,
- vision disturbances,
- tinnitus (pulsation of noises in the ears),
- cough,
- dry mouth,
- muscle cramps; changes in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, hypoglycaemia (very low blood sugar level) in case of diabetic patients, increased blood urea, and increased blood creatinine.

Rare (may affect up to 1 in 100 people):
- changes in laboratory parameters: increased level of liver enzymes, high level of serum bilirubin.

Very rare (may affect up to 1 in 10,000 people):
- confusion,
- eosinophilic pneumonia (a rare type of pneumonia),
- rhinitis (blocked up or runny nose),
- acne rash/allergic reaction,
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower 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. If you have these symptoms contact your doctor as soon as possible.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to company website https://www.servier.com.pk/ or Drug Regulatory Authority of Pakistan http://dra.gov.pk/ By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Coversyl 4 mg

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 medicine via wastewaster or household waste. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help to protect the environment.

6. Content of the pack and other information

What Coversyl 4 mg contains

The active substance is perindopril tert-butylamine. One tablet contains 4 mg perindopril tert-butylamine.

The other ingredients are: microcrystalline cellulose, lactose monohydrate, hydrophobic colloidal silica, magnesium stearate, aluminium copper complexes of chlorophyllins lake.

What Coversyl 4 mg looks like and contents of the pack

Coversyl 4 mg tablets are light-green, rod-shaped, engraved with 4 mg on one face and scored on both edges. The tablets can be divided into equal halves. The tablets are available in blister packs (PVC/Aluminium) of 10 tablets.

Marketing Authorisation Holder and Manufacturer

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04235879500-6

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