Package leaflet: Information for the patient

Coversyl 5 mg film-coated tablets
perindopril arginine

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, pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Coversyl is and what it is used for
2. What you need to know before you take Coversyl
3. How to take Coversyl
4. Possible side effects
5. How to store Coversyl
6. Content of the pack and other information

1. What Coversyl is and what it is used for

Coversyl 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 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 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 an operation to improve the blood supply to the heart by widening the vessels that supply it.

2. What you need to know before you take Coversyl

Do not take Coversyl
- 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 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 better to avoid Coversyl 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.

Warning and precaution
If any of the following apply to you please talk to your doctor or pharmacist or nurse before taking Coversyl 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 artery supplying the kidney with blood),
- have any other heart problems,
- have liver problems,
- have kidney problems or if you are receiving dialysis,
- 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 to undergo anaesthesia 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 been told by your doctor that you have an intolerance to some sugars,
- are taking any of the following medicines used to treat high blood pressure:
  - an "angiotensin II receptor blocker" (ARBs) (also known as sartans - 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".
- are of black origin since 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.

<u>Angioedema</u>
Angioedema (a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) has been reported in patients treated with ACE inhibitors, including Coversyl. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Coversyl and see a doctor immediately. See also section 4.

You must tell your doctor if you think you are (<u>or might become</u>) pregnant. Coversyl 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).

Children and adolescent
The use of perindopril in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Coversyl
Please tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines.
Treatment with Coversyl can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. These include:
- other medicines for high blood pressure, including angiotensin II receptor blocker (ARB), aliskiren (see also information under the headings "Do not take Coversyl" and "Warning and precaution"), or diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- potassium-sparing drugs used in the treatment of heart failure : eplerenone and spironolactone at doses between 12,5 mg to 50 mg by day,
- lithium for mania or depression,
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin or metformin),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),

- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus),
- trimethoprim (for the treatment of infections),
- estramustine (used in cancer therapy),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that make the blood vessels become wider),
- heparin (medicines used to thin blood),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).

Coversyl with food and drink
It is preferable to take Coversyl 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 you are (or might become) pregnant. Your doctor will normally advise you to stop taking Coversyl before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Coversyl. Coversyl 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 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
Coversyl 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 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.

3. How to take Coversyl

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, before a meal. Your doctor will decide on the correct dose for you.

The recommended dosages are as follows:
High blood pressure: the usual starting and maintenance dose is 5 mg once daily. After one month, this can be increased to 10 mg once a day if required. 10 mg a day is the maximum recommended dose for high blood pressure.
If you are 65 or older, the usual starting dose is 2.5 mg once a day. After a month this can be increased to 5 mg once a day and then if necessary to 10 mg once daily.

Heart failure: the usual starting dose is 2.5 mg once daily. After two weeks, this can be increased to 5 mg once a day, which is the maximum recommended dose for heart failure.
Stable coronary artery disease: the usual starting dose is 5 mg once daily. After two weeks, this can be increased to 10 mg once daily, which is the maximum recommended dose in this indication.
If you are 65 or older, the usual starting dose is 2.5 mg once a day. After a week this can be increased to 5 mg once a day and after a further week to 10 mg once daily.

Use in children and adolescent
Use in children and adolescent is not recommended.

If you take more Coversyl 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
It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Coversyl, 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
As the treatment with Coversyl 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 “Warning and precaution”) (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 wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm) (Uncommon - may affect up to 1 in 100 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 (sensation of noises in the ears),
- cough,
- shortness of breath (dyspnoea),
- gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation),
- allergic reactions (such as skin rashes, itching),
- muscle cramps,
- feeling of weakness.

Uncommon (may affect to 1 in 100 people):
- mood swings,
- sleep disturbances,
- dry mouth,
- intense itching or severe skin rashes,
- formation of blister clusters over the skin,
- kidney problems,
- impotence,
- sweating,
- excess of 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,
- change 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 1000 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),
- acute renal failure,
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets.

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 via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Coversyl

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 bottle. The expiry date refers to the last day of that month.
Keep the bottle tightly closed in order to protect from moisture.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer used. These measures will help to protect the environment.

6. Content of the pack and other information

What Coversyl 5 mg contains

- The active substance is perindopril arginine. One film-coated tablet contains 3.395 mg perindopril (corresponding to 5 mg perindopril arginine).
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, sodium starch glycolate (type A), and in the tablet film-coating: glycerol, hypromellose, copper chlorophyllin, macrogol 6000, magnesium stearate, titanium dioxide.

What Coversyl 5 mg looks like and contents of the pack

Coversyl 5 mg tablets are light-green, rod-shaped film-coated tablets engraved with on one face and scored on both edges. The tablet can be divided into equal halves.
The tablets are available in box of 5, 10, 14, 20, 30, 50, 60 (60 or 2 containers of 30), 90 (90 or 3 containers of 30), 100 (100 or 2 containers 50), 120 (120 or 4 containers of 30) or 500 tablets (500 or 10 containers of 50).
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
<[To be completed nationally]>

For RMS (France):
Les Laboratoires Servier
50 rue Carnot
92284 Suresnes cedex – France

Manufacturer
Les Laboratoires Servier Industrie
905 route de Saran
45520 Gidy – France

and

Servier (Ireland) Industries Ltd
Gorey Road
Arklow - Co. Wicklow – Ireland

and

Anpharm Przedsiêbiorstwo Farmaceutyczne S.A.
03-236 Warszawa
ul. Annopol 6B – Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Coversum-Arginin 5 mg-Filmtabletten
Belgium	COVERSYL 5 mg
Cyprus	COVERSYL 5 mg
Czech Republic	Prestarium Neo
Denmark	COVERSYL NOVUM 5 mg
Estonia	Prestarium Arginine 5 mg
Finland	COVERSYL NOVUM 5 mg
France	COVERSYL 5 mg comprimé pelliculé sécable
Germany	COVERSUM Arginin 5 mg
Greece	COVERSYL 5 mg
Hungary	ARMIX Arginin 5 mg
Iceland	COVERSYL NOVUM 5 mg
Ireland	COVERSYL Arginine 5 mg film-coated tablets
Italy	COVERSYL 5 mg
Latvia	PRESTARIUM 5 mg
Lithuania	PRESTARIUM 5 mg
Luxembourg	COVERSYL 5 mg
Malta	COVERSYL 5 mg
Netherlands	COVERSYL arg 5 mg
Norway	PERINDOPRILARGININ SERVIER 5 mg
Poland	PRESTARIUM 5 mg
Portugal	COVERSYL 5 mg
Slovakia	PRESTARIUM A 5 mg
Slovenia	BIOPREXANIL 5 mg flimsko oblozene tablete
Sweden	COVERSYL NOVUM 5 mg
United Kingdom	COVERSYL Arginine 5 mg

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