

PACKAGE LEAFLET: INFORMATION FOR THE USER
Coversyl® Arginine Plus 5mg/1.25mg film-coated tablets
(perindopril arginine and indapamide)

Your medicine is available as the above name but will be referred to as Coversyl Arginine Plus 5mg/1.25mg throughout this leaflet.

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. See section 4.

What is in this leaflet:

1. What Coversyl Arginine Plus 5mg/1.25mg is and what it is used for
2. What you need to know before you take Coversyl Arginine Plus 5mg/1.25mg
3. How to take Coversyl Arginine Plus 5mg/1.25mg
4. Possible side effects
5. How to store Coversyl Arginine Plus 5mg/1.25mg
6. Contents of the pack and other information

1. What Coversyl Arginine Plus 5mg/1.25mg is and what it is used for

Coversyl Arginine Plus 5mg/1.25mg is a combination of two active ingredients, perindopril and indapamide. It is an anti-hypertensive and is used in the treatment of high blood pressure (hypertension) in adults.

Perindopril belongs to a class of medicines called ACE inhibitors. These work by widening the blood vessels, which makes it easier for your heart to pump blood through them. Indapamide is a diuretic. Diuretics increase the amount of urine produced by the kidneys. However, indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced. Each of the active ingredients reduces blood pressure and they work together to control your blood pressure.

2. What you need to know before you take Coversyl Arginine Plus 5mg/1.25mg

Do not take Coversyl Arginine Plus 5mg/1.25mg

- if you are allergic to perindopril or any other ACE inhibitor, or to indapamide or any other sulfonamides or any of the other ingredients of this medicine (listed in section 6),
- if you have experienced symptoms such as wheezing, swelling of the face or tongue, 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 have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren,
- if you have severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain),
- if you have a severe kidney disease where the blood supply to your kidneys is reduced (renal artery stenosis),
- if you are receiving dialysis, or any other type of blood filtration. Depending on the machine that is used, Coversyl Arginine Plus 5mg/1.25mg may not be suitable for you,
- if you have low blood potassium,
- if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing),
- if you are more than 3 months pregnant (It is also better to avoid Coversyl Arginine Plus 5mg/1.25mg in early pregnancy - see "Pregnancy section"),
- if you have taken or are currently taking sacubitril/valsartan, a medicine for heart failure, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased (see "Warnings and Precautions" and "Other medicines and Coversyl Arginine Plus 5mg/1.25mg").

Warnings and precautions

Talk to your doctor or pharmacist before taking Coversyl Arginine Plus 5mg/1.25mg:

- 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),
- if you have heart failure or any other heart problems,
- if you have kidney problems, or if you are receiving dialysis
- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Coversyl Arginine Plus 5mg/1.25mg. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this.
- if you have muscle disorders including muscle pain, tenderness, weakness or cramps,
- if you have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- if you have liver problems,
- if you suffer from a collagen disease (skin disease) such as systemic lupus erythematosus or scleroderma,
- if you have atherosclerosis (hardening of the arteries),
- if you suffer from hyperparathyroidism (overactive parathyroid gland),
- if you suffer from gout,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you take lithium or potassium-sparing drugs (spironolactone, triamterene) or potassium supplements as their use with Coversyl Arginine Plus 5mg/1.25mg should be avoided (see "Taking other medicines"),
- if you are elderly,
- if you have had photosensitivity reactions,
- if you have a severe allergic reaction with swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema). This may occur at any time during treatment. If you develop such symptoms, you should stop taking the treatment and see a doctor immediately.
- if you 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 Arginine Plus".

- if you 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,
- if you are a haemodialysis patient dialysed with high-flux membranes,
- if you are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (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 and for cancer),
 - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.
 - linagliptin, saxagliptin, sitagliptin, vildagliptin and other drugs belonging to the class of the also called gliptins (used to treat diabetes).

Angioedema

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 Arginine Plus. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Coversyl Arginine Plus and see a doctor immediately. See also section 4.

You must tell your doctor if you think that you are (or might become) pregnant. Coversyl Arginine Plus 5mg/1.25mg 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").

When you are taking Coversyl Arginine Plus 5mg/1.25mg, you should also inform your doctor or the medical staff:

- if you are to undergo anaesthesia and/or surgery,
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you are to undergo dialysis or LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- if you are to undergo a medical test that requires injection of an iodinated contrast agent (a substance that makes organs like kidney or stomach visible on an X-ray),
- if you have changes in your vision or pain in one or both of your eyes while taking Coversyl Arginine Plus 5mg/1.25mg. This could be a sign that you are developing glaucoma, increased pressure in your eye(s). You should discontinue Coversyl Arginine Plus 5mg/1.25mg treatment and seek medical attention.

Athletes should be aware that Coversyl Arginine Plus 5mg/1.25mg contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

Children and adolescents

Coversyl Arginine Plus 5mg/1.25mg should not be given to children and adolescents.

Other medicines and Coversyl Arginine Plus 5mg/1.25mg

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

You should avoid Coversyl Arginine Plus 5mg/1.25mg with:

- lithium (used to treat mania or depression),
- aliskiren (medicine used to treat hypertension) if you have no diabetes mellitus or kidney problems,
- potassium-sparing diuretics (e.g. triamterene, amiloride), potassium salts, other drugs which can increase potassium in your body (such as heparin, a medicine used to thin blood to prevent clots; trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria),
- estramustine (used in cancer therapy),
- other medicines used to treat high blood pressure: angiotensin-converting-enzyme inhibitors and angiotensin receptor blockers.

Treatment with Coversyl Arginine Plus 5mg/1.25mg can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- other medicines for treating high blood pressure including angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Coversyl Arginine Plus 5mg/1.25mg" and "Warnings and precautions" or diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs used in the treatment of heart failure: eplerenone and spironolactone at doses between 12.5 mg to 50mg per day,
- 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 Arginine Plus 5mg/1.25mg" and "Warnings and precautions".
- anaesthetic medicines,
- iodinated contrast agent,
- antibiotics used to treat bacterial infections (e.g. moxifloxacin, sparfloxacin, erythromycin by injection),
- methadone (used to treat addiction),
- procainamide (for the treatment of an irregular heart beat),
- allopurinol (for the treatment of gout),
- antihistamines used to treat allergic reactions, such as hay fever (e.g. mizolastine, terfenadine, astemizole)
- corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis,
- immunosuppressants used for the treatment of auto-immune disorders or following transplant surgery to prevent rejection (e.g. ciclosporin, tacrolimus),
- halofantrine (used to treat certain types of malaria),
- pentamidine (used to treat pneumonia),
- injectable gold (used to treat rheumatoid polyarthritis),
- vincamine (used to treat symptomatic cognitive disorders in elderly including memory loss),
- bepridil (used to treat angina pectoris),
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, digitalis, bretylium),
- cisapride, diphemanil (used to treat gastric and digestive problems),
- digoxin or other cardiac glycosides (for the treatment of heart problems),
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis),
- medicines to treat diabetes such as insulin, metformin or gliptins,
- calcium including calcium supplements,