Coversyl® Arginine Plus 5mg/1.25mg film-coated tablets

3387
22.02.24[3]

(perindopril arginine / indapamide)

PATIENT INFORMATION 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.

The name of your medicine is Coversyl Arginine Plus 5mg/1.25mg film-coated Tablets but will be referred to as Coversyl Arginine Plus 5mg/1.25mg throughout this leaflet.

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 sulfonamide 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 5mg/1.25mg”.
- 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 5mg/1.25mg. This may occur at any time during treatment. If you develop such symptoms, you should stop taking Coversyl Arginine Plus 5mg/1.25mg 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 “Take special care with Coversyl Arginine Plus 5mg/1.25mg”) 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 50 mg 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,
- stimulant laxatives (e.g. senna),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. acetylsalicylic acid (a substance present in many medicines used to relieve pain and lower fever, as well as to prevent blood clotting)),
- amphotericin B by injection (to treat severe fungal disease),

- medicines used to treat mental disorders such as depression, anxiety, schizophrenia… (e.g. tricyclic antidepressants, neuroleptics (such as amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol)),
- tetracosactide (to treat Crohn's disease),
- trimethoprim (for the treatment of infections),
- vasodilators including nitrates (products that make the blood vessels become wider),
- medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline).

Coversyl Arginine Plus 5mg/1.25mg with food and drink
It is preferable to take Coversyl Arginine Plus 5mg/1.25mg 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 Arginine Plus 5mg/1.25mg before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Coversyl Arginine Plus 5mg/1.25mg. Coversyl Arginine Plus 5mg/1.25mg 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.

Breast-feeding
Coversyl Arginine Plus 5mg/1.25mg is not recommended if you are breast-feeding.
Tell your doctor immediately if you are breast-feeding or about to start breast-feeding. See your doctor immediately.

Driving and using machines
Coversyl Arginine Plus 5mg/1.25mg usually does not affect alertness but different reactions such as dizziness or weakness in relation to the decrease in blood pressure may occur in certain patients. If affected, your ability to drive or to operate machinery may be impaired.

Coversyl Arginine Plus 5mg/1.25mg contains lactose monohydrate
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Coversyl Arginine Plus 5mg/1.25mg contains sodium
Coversyl Arginine Plus 5mg/1.25mg contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE COVERSYL ARGININE PLUS 5MG/1.25MG
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one tablet once a day. Your doctor may decide to modify the dosage regimen if you suffer from renal impairment. Take your tablet preferably in the morning and before a meal. Swallow the tablet with a glass of water.

If you take more Coversyl Arginine Plus 5mg/1.25mg than you should
If you take too many tablets, contact your doctor or nearest hospital casualty department immediately. The most likely effect in case of overdose is low blood pressure. If marked low blood pressure occurs (associated with nausea, vomiting, cramps, dizziness, sleepiness, mental confusion, changes in the amount of urine produced by kidneys), lying down with the legs raised can help.

If you forget to take Coversyl Arginine Plus 5mg/1.25mg
It is important to take your medicine every day as regular treatment is more effective. However, if you forget to take a dose of Coversyl Arginine Plus 5mg/1.25mg, 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 Arginine Plus 5mg/1.25mg
As the treatment for high blood pressure 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 or pharmacist.

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:
- Severe dizziness or fainting due to low blood pressure (Common - may affect up to 1 in 10 people),
- Bronchospasm (tightening of the chest, wheezing and shortness of breath (Uncommon) (may affect up to 1 in 100 people),
- 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 skin reactions including erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs) or intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions (Very rare) (may affect up to 1 in 10,000 people),
- Cardiovascular disorders (irregular heart beat, angina pectoris (pains to the chest, jaw and back, brought on by physical effort), 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),
- 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),
- Life-threatening irregular beat (Not known),
- Disease of the brain caused by liver illness (Hepatic encephalopathy) (Not known),
- Muscle weakness, cramps, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (Not known).

In decreasing order of frequency, side effects can include:
- Common (may affect up to 1 in 10 people):
  Low potassium in the blood, skin reactions in subjects predisposed to allergic and asthmatic reactions, 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), cramps, feeling of tiredness.
- Uncommon (may affect up to 1 in 100 people):
  Mood swings, depression, sleep disturbances, urticaria, purpura (red pinpoints on skin), blister cluster, kidney problems, impotence (inability to obtain or maintain an erection), sweating, an excess of eosinophils (a type of white blood cells), change in laboratory parameters:
  high blood level of potassium reversible on discontinuation, low blood level of sodium that may lead to dehydration and low blood pressure, somnolence, fainting, palpitations (awareness of your heartbeat), tachycardia (fast heartbeat), hypoglycaemia (very low blood sugar level) in case of diabetic patients, vasculitis (inflammation of blood vessels), dry mouth, photosensitivity reactions (increased sensitivity of the skin to sun), arthralgia Ooint pain), myalgia (muscle pain), chest pain, malaise, oedema peripheral, fever, increased blood urea, increased blood creatinine, fall.

- Rare (may affect up to 1 in 1000 people):
  Psoriasis worsening, changes in laboratory parameters: low chloride in the blood, low magnesium in the blood, increased level of liver enzymes, high level of serum bilirubin, fatigue, flushing, decrease or absence urine output, acute renal failure.
  Dark urine, feeling sick (nausea) or being sick (vomiting), muscle cramps, confusion and seizures.
  These may be symptoms of a condition called SIADH (inappropriate antidiuretic hormone secretion).

- 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), severe kidney problems, changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, high level of calcium in the blood, abnormal hepatic function.

- Not known (frequency cannot be estimated from the available data):
  Abnormal ECG heart tracing, changes in laboratory parameters: high uric acid levels and high sugar levels in the blood, short sightedness (myopia), vision blurred, visual impairment, decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma), discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon). If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.

Disorders of the blood, kidney, liver or pancreas and changes in laboratory parameters (blood tests) can occur. Your doctor may need to give you blood tests to monitor your condition.

If you have these symptoms contact your doctor as soon as possible.

Reporting of suspected adverse reactions
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 via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE COVERSYL ARGININE PLUS 5MG/1.25MG
Keep out of the sight and reach of children.
Do not use Coversyl Arginine Plus 5mg/1.25mg after the expiry date which is stated on the carton and container. The expiry date refers to the last day of that month.
Keep container tightly closed in order to protect from moisture.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
If your tablets become discoloured or show any other signs of deterioration, consult your doctor or pharmacist who will tell you what to do.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Coversyl Arginine Plus 5mg/1.25mg contains
- The active substances are perindopril arginine and indapamide.
- Each film-coated tablet contains 3.395 mg perindopril corresponding to 5 mg perindopril arginine and 1.25mg indapamide.
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate (E470B), maltodextrin, colloidal anhydrous silica (E551), sodium starch glycolate (type A), and in the tablet film-coating: glycerol (E422), hypromellose (E464), macrogol 6000, magnesium stearate (E470B), titanium dioxide (E171).

What Coversyl Arginine Plus 5mg/1.25mg looks like and contents of the pack
Coversyl Arginine Plus 5mg/1.25mg are white, rod-shaped, film-coated tablets with no markings on either side. The tablets are available in a container of 30 tablets.

Manufacturer and Product Licence holder
Manufactured by
Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France.
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