

PACKAGE LEAFLET: INFORMATION FOR THE USER

COVERSYL® Arginine PLUS 10 mg / 2.5 mg

Film-coated Tablets

perindopril arginine/indapamide

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT COVERSYL ARGININE PLUS 10 MG/2.5 MG IS AND WHAT IT IS USED FOR

What is COVERSYL ARGININE PLUS 10 mg/2.5 mg?

COVERSYL ARGININE PLUS 10 mg/2.5 mg is a combination of two active ingredients, perindopril and indapamide. It is an anti-hypertensive and is used to treat high blood pressure (hypertension). COVERSYL ARGININE PLUS 10 mg/2.5 mg is prescribed for patients already receiving perindopril 10 mg and indapamide 2.5 mg from separate tablets, these patients may instead receive one tablet of COVERSYL ARGININE PLUS 10 mg/2.5 mg which contains both ingredients.

What is COVERSYL ARGININE 10 mg/ 2.5 mg used for?

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. BEFORE YOU TAKE COVERSYL ARGININE PLUS 10 MG/2.5 MG

Do not take COVERSYL ARGININE PLUS 10 mg/2.5 mg

- If you are allergic to perindopril or any other ACE inhibitor, or to indapamide or any other sulphonamides or any of the other ingredients of COVERSYL ARGININE PLUS 10 mg/2.5 mg,
- 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 severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain),
- If you have a kidney disease or are receiving dialysis,
- If you have low or high 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 10 mg/2.5 mg in early pregnancy – see “Pregnancy and Breast-feeding”),
- If you are breast-feeding.

Take special care with COVERSYL ARGININE PLUS 10 mg/2.5 mg

If any of the following apply to you please talk to your doctor before taking COVERSYL ARGININE PLUS 10 mg/2.5 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 artery supplying the kidney with blood),
- If you have any other heart problems,
- 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 diuretics (spironolactone, triamterene) as their use with COVERSYL ARGININE PLUS 10 mg/2.5 mg should be avoided (see “Taking other medicines”).

You must tell your doctor if you think that you are (*or might become*) pregnant. COVERSYL ARGININE PLUS 10 mg/2.5 mg 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 10 mg/2.5 mg, 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 kidneys or stomach visible on an X-ray)

Athletes should be aware that COVERSYL ARGININE PLUS 10 mg/2.5 mg contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

COVERSYL ARGININE PLUS 10 mg/2.5 mg should not be given to children.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should avoid COVERSYL ARGININE PLUS 10 mg/2.5 mg with:

- Lithium (used to treat depression),
- Potassium-sparing diuretics (spironolactone, triamterene), potassium salts.

Treatment with COVERSYL ARGININE PLUS 10 mg/2.5 mg can be affected by other medicines. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- Other medicines to treat high blood pressure,
- Procainamide (for treatment of an irregular heart beat),
- Allopurinol (for the treatment of gout),
- Terfenadine or astemizole (antihistamines for hay fever or allergies),
- 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),
- Medicines for the treatment of cancer,
- Erythromycin by injection (an antibiotic),
- Halofantrine (used to treat certain types of malaria),
- Pentamidine (used to treat pneumonia),
- Vincamine (used to treat symptomatic cognitive disorders in elderly including memory loss),
- Bepidil (used to treat angina pectoris),
- Sultopride (for the treatment of psychoses),
- Medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol),
- 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 or metformin
- Calcium including calcium supplements,
- Stimulant laxatives (e.g. senna),
- Non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high dose salicylates (e.g. aspirin),
- Amphotericin B by injection (to treat severe fungal disease),
- Medicines to treat mental disorders such as depression, anxiety, schizophrenia...(e.g. tricyclic antidepressants, neuroleptics),
- Tetracosactide (to treat Crohn's disease).

Taking COVERSYL ARGININE PLUS 10 mg/2.5 mg with food and drink

It is preferable to take COVERSYL ARGININE PLUS 10 mg/2.5 mg just before a meal.

Pregnancy and breast-feeding

Ask your doctor or pharmacist before taking any medicine.

Pregnancy

You must tell your doctor if you think you are (*or might become*) pregnant.

You doctor will normally advise you to stop taking COVERSYL ARGININE PLUS 10 mg/2.5 mg 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 10 mg/2.5 mg. COVERSYL ARGININE PLUS 10 mg/2.5 mg 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

Tell your doctor if you are breast-feeding or are about to start breast-feeding. COVERSYL ARGININE PLUS 10 mg/2.5 mg is contra-indicated 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.

See your doctor immediately.

Driving and using machines

COVERSYL ARGININE PLUS 10 mg/2.5 mg does not usually 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.

Important information about some of the ingredients of COVERSYL ARGININE PLUS 10 mg/2.5 mg

COVERSYL ARGININE PLUS 10 mg/2.5 mg contains lactose (a type of sugar). 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 ARGININE PLUS 10 MG/2.5 MG

Always take COVERSYL ARGININE PLUS 10 mg/2.5 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one tablet daily. 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 10 mg/2.5 mg than you should

If you take too many tablets, contact your doctor or nearest hospital casualty immediately. The most likely effect in case of an overdose is low blood pressure. If marked low blood pressure occurs (symptoms such as dizziness or faintness), lying down with your legs raised can help.

If you forget to take COVERSYL ARGININE PLUS 10 mg/2.5 mg

It is important to take your medicine everyday as regular treatment is more effective. However, if you forget to take a dose of COVERSYL ARGININE PLUS 10 mg/2.5 mg, take the next dose at the usual time. Do not take a double dose to make up for the forgotten dose.

If you stop taking COVERSYL ARGININE PLUS 10 mg/2.5 mg

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 product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, COVERSYL ARGININE PLUS 10 mg/2.5 mg can cause side effects, although not everyone gets them.

If you experience any of the following, stop taking the medicinal product at once and tell your doctor immediately:

- Swelling of the face, lips, mouth, tongue or throat, difficulty in breathing.
- Severe dizziness or fainting.
- Unusually fast or irregular heart beat.

In decreasing order of frequency, side effects can include:

- Common (occur in fewer than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, vertigo, pins and needles, vision disturbances, tinnitus (sensation of noise in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorders (nausea, vomiting abdominal pain, taste disturbances, dry mouth, dyspepsia or difficulty in digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), muscle cramps, feeling of tiredness.
- Uncommon (occur in fewer than 1 in 100 users but in more than 1 in 1000 users): mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), angioedema (symptoms such as wheezing, swelling of the face or

tongue), urticaria, purpura (red pinpoint spots on skin), kidney problems, impotence, sweating.

- Very rare (occur in fewer than 1 in 10,000 users): confusion, cardiovascular disorders (irregular heartbeat, angina, heart attack), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), severe skin manifestations such as multiforme. If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse. Cases of photosensitivity reactions (change in skin appearances) after exposure to the sun or artificial UVA have also been reported. 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. In cases of hepatic insufficiency (liver problems), there is a possibility of onset of hepatic encephalopathy (degenerative disease in the brains).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE COVERSYL ARGININE PLUS 10 MG/2.5 MG

Keep out of the reach and sight of children.

Do not use COVERSYL ARGININE PLUS 10 mg/2.5 mg 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 waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What COVERSYL ARGININE PLUS 10 mg/2.5 mg contains

- The active substances are perindopril arginine and indapamide. One film-coated tablet contains 10 mg perindopril arginine (corresponding to 6.79 mg perindopril) and 2.5 mg indapamide.
- The other ingredients in the tablet core are: lactose monohydrate, microcrystalline cellulose, magnesium stearate (E470B), maltodextrin, anhydrous colloidal 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 10 mg/2.5 mg looks like and the contents of the pack

COVERSYL ARGININE PLUS 10 mg/2.5 mg film-coated tablets are white, round, film-coated tablets. One film-coated tablet contains 10 mg perindopril arginine and 2.5 mg indapamide. The tablets are in containers of 30 tablets.

Manufacturer:

Les Laboratoires Servier, 905 route de Saran, 45520 Gidy, France and Servier (Ireland) Industries LTD, Gorey Road, Arklow, Co. Wicklow, Ireland.

Product procured from within the EU and repackaged and distributed by the Parallel Product Authorization holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Parallel Product Authorisation Number: PPA 465/67/7

COVERSYL is a registered trademark of BIOFARMA, 22 rue Garnier, F-92200 Neuilly-sur-Seine, France.

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

Belgium	NOLITERAX 10mg/2,5mg
Bulgaria	NOLITERAX 10mg/2.5mg
Cyprus	NOLITERAX 10mg/2.5mg
Czech Republic	NOLITERAX 10mg/2,5mg
Denmark	NOLITERAX 10mg/2,5mg
Estonia	NOLITERAX 10mg/2.5mg
Finland	COVERSYL COMP NOVUM 10mg/2,5mg
France	NOLITERAX 10mg/2,5mg
Greece	NOLITERAX 10mg/2,5mg
Hungary	Coverex-AS Komb Forte 10mg/2,5mg
Iceland	NOLITERAX 10mg/2.5mg
Ireland	Coversyl Arginine Plus 10mg/2.5mg
Italy	NOLITERAX 10mg/2,5mg
Latvia	NOLITERAX 10mg/2.5mg
Lithuania	NOLITERAX 10mg/2,5mg pėvele dengtos tabletės
Luxembourg	NOLITERAX 10mg/2,5mg
Malta	NOLITERAX 10mg/2.5mg
The Netherlands	COVERSYL PLUS arg 10mg/2.5mg
Poland	Peryndoporyl arginine + Indapamid Servier
Portugal	PRETERAX 10mg/2,5mg

Romania	NOLITERAX 10mg/2,5mg
Slovakia	NOLITERAX 10mg/2.5mg
Slovenia	NOLITERAX 10mg/2,5mg filmsko obložene tablet
Spain	NOLITERAX 10mg/2,5mg
United Kingdom	Coversyl Arginine Plus 10mg/2.5mg film-coated tablets

Date of leaflet preparation by PCO Manufacturing: May 2014