

Leaflet Details

Licence Number: PPA1562/063/002

Leaflet size: 210mm x 345mm, Portrait double sided - 2 columns on each side

Column width: 97.5mm

Text Free Border: 5mm (around edge & between columns)

Font: Arial

Font Size: Title = 15pt
Generic Name = 12pt
Main Section Headings = 10pt
Sub Headings = 8pt
Main Text = Font 8pt / Leading 9pt
Statement for Blind = 12pt

Colour: Black print on white paper

Irish Leaflet: Servier, October 2014

LTT Revision date: 23/09/2016

Ref: 063/002/230916/1/F & Ref: 063/002/230916/1/B =
Coversyl Arginine Plus 10mg/ 2.5mg Film-coated Tablets (Front & Back)

This is the final mock-up.

This leaflet has been user tested.

COVERSYL® Arginine Plus 10mg/ 2.5mg Film-coated Tablets

(perindopril arginine/ indapamide)

Package Leaflet: Information for the user

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.

In this leaflet:

- 1 What COVERSYL ARGININE PLUS 10mg/2.5mg is and what it is used for
- 2 Before you take COVERSYL ARGININE PLUS 10mg/2.5mg
- 3 How to take COVERSYL ARGININE PLUS 10mg/2.5mg
- 4 Possible side effects
- 5 How to store COVERSYL ARGININE PLUS 10mg/2.5mg
- 6 Further information

1 What COVERSYL ARGININE PLUS 10mg/2.5mg is and what it is used for

What is COVERSYL ARGININE PLUS 10mg/2.5mg?

COVERSYL ARGININE PLUS 10mg/2.5mg 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). COVERSYL ARGININE PLUS 10mg/2.5mg 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 10mg/2.5mg which contains both ingredients.

What is COVERSYL ARGININE PLUS 10mg/2.5mg 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 10mg/2.5mg

Do not take COVERSYL ARGININE PLUS 10mg/2.5mg

- * 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 10mg/2.5mg,
- * 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 kidney disease or if you 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 10mg/2.5mg in early pregnancy - see "Pregnancy and Breast-feeding"),
- * if you are breast-feeding.

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

If any of the following apply to you please talk to your doctor before taking COVERSYL ARGININE PLUS 10mg/2.5mg:

- * 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 10mg/2.5mg should be avoided (see "Taking other medicines"),
- * 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 10mg/2.5mg".

You must tell your doctor if you think that you are (or might become) pregnant. COVERSYL ARGININE PLUS 10mg/2.5mg 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 breastfeeding").

When you are taking COVERSYL ARGININE PLUS 10mg/2.5mg, 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)

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

COVERSYL ARGININE PLUS 10mg/2.5mg 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 10mg/2.5mg with:

- * lithium (used to treat depression),
- * potassium-sparing diuretics (spironolactone, triamterene), potassium salts.

Treatment with COVERSYL ARGININE PLUS 10mg/2.5mg 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 10mg/2.5mg" and "Take special care with COVERSYL ARGININE PLUS 10mg/2.5mg"),
- * procainamide (for the 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),
- * bepridil (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 10mg/2.5mg with food and drink

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 10mg/2.5mg 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 10mg/2.5mg. COVERSYL ARGININE PLUS 10mg/2.5mg 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 about to start breast-feeding. COVERSYL ARGININE PLUS 10mg/2.5mg 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.

COVERSYL® Arginine Plus 10mg/2.5mg film-coated tablets

(perindopril arginine/ indapamide)

Package Leaflet: Information for the user (continued)

Driving and using machines

COVERSYL ARGININE PLUS 10mg/2.5mg 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 10mg/2.5mg

COVERSYL ARGININE PLUS 10mg/2.5mg 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 10mg/2.5mg

Always take COVERSYL ARGININE PLUS 10mg/2.5mg 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 10mg/2.5mg than you should

If you take too many tablets, contact your doctor or nearest hospital casualty immediately. The most likely effect in case of 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 10mg/2.5mg

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 10mg/2.5mg, 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 10mg/2.5mg

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 10mg/2.5mg can cause side effects, although not everybody 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,
- * unusual 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 noises 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 of 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 pinpoints on skin), kidney problems, impotence, sweating,

- * Very rare (occur in fewer than 1 in 10,000 users): confusion, cardiovascular disorders (irregular heart beat, angina, heart attack), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), severe skin manifestations such as erythema multiforme. If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse. Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported.

- * Not known (frequency cannot be estimated from the available data): fainting, life-threatening irregular beat (Torsade de Pointes), abnormal ECG heart tracing, increased levels of liver enzymes.

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 brain).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store COVERSYL ARGININE PLUS 10mg/2.5mg

Keep out of the sight and reach of children.

Do not use COVERSYL ARGININE PLUS 10mg/2.5mg after the expiry date which is stated on the carton and container. The expiry date refers to the last day of that month.

Keep the 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.

6 Further information

What COVERSYL ARGININE PLUS 10mg/2.5mg 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, maltodextrin, magnesium stearate (E470B), anhydrous colloidal silica, Sodium starch glycolate type A
- film coating: glycerol (E422), hypromellose (E464), macrogol 6000, titanium dioxide (E171) and magnesium stearate (E470B)

What COVERSYL ARGININE PLUS 10mg/2.5mg looks like and contents of the pack

COVERSYL ARGININE PLUS 10mg/2.5mg film-coated tablets are white, round film-coated tablets. The tablets are available in containers of 30 tablets.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18 Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Re-packaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Manufactured by:

Les Laboratoires Servier Industrie (LSI) 905 route de Saran 45520 Gidy - France
or
Servier (Ireland) Industries Ltd (SII), Gorey Road, Arklow - Co. Wicklow, Ireland
or
ANPHARMA Przedsiębiorstwo Farmaceutyczne S.A. ul. Annopol 6B 03-236 Warsaw - Lengyelország

Coversyl is a registered trademark of BIOFARMA.

POM PPA 1562/063/002 Coversyl Arginine Plus

Revision date: 23/09/2016

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0) 1527 505414 for help.

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

Belgium	PRETERAX 10mg/2,5mg
Bulgaria	NOLIPREL Bi-FORTE
Cyprus	COVERSYL PLUS ARGININE 10 mg/ 2,5 mg
Czech Republic	Prestarium Neo Combi 10mg/2,5mg
Denmark	NOLITERAX
Estonia	NOLITERAX 10mg/2.5mg
Finland	COVERSYL COMP NOVUM 10mg/2,5mg
France	BIPRETERAX 10mg/2,5mg comprimé pelliculé
Greece	Preterax 10mg/2,5mg
Hungary	NOLITERAX 10mg/2,5mg
Iceland	NOLITERAX 10mg/2,5mg
Ireland	COVERSYL ARGININE PLUS 10mg/2.5mg
Italy	NOLITERAX 10/2,5
Latvia	NOLITERAX 10mg/2.5mg apvalkotās tablets
Lithuania	NOLITERAX 10mg/2,5mg plėvele dengtos tabletės
Luxembourg	PRETERAX 10mg/2,5mg
Malta	COVERSYL PLUS 10mg/2.5mg
The Netherlands	COVERSYL PLUS arg 10mg/2,5mg
Poland	NOLIPREL Bi-FORTE
Portugal	PRETERAX
Romania	NOLITERAX 10 mg /2,5 mg
Slovakia	NOLIPREL Bi-FORTE A
Slovenia	BIONOLIPREL 10mg/2,5mg filmsko obložene tablete
United Kingdom	Coversyl Arginine Plus 10mg/2.5mg