

PACKAGE LEAFLET: INFORMATION FOR THE USER

Coversyl® Arginine 5mg 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.

Your medicine is available using the above name, but will be referred to as 'Coversyl Arginine' throughout this leaflet.

What is in this leaflet:

- What Coversyl Arginine is and what it is used for
- What you need to know before you take Coversyl Arginine
- How to take Coversyl Arginine
- Possible side effects
- How to store Coversyl Arginine
- Content of the pack and other information

1. What Coversyl Arginine is and what it is used for

Coversyl Arginine 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 Arginine 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 Arginine

Do not take Coversyl Arginine

- 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 Arginine in early pregnancy – see pregnancy section),
- if you have diabetes mellitus or kidney problems and you are treated with aliskiren.

Warning and precaution

If any of the following apply to you please talk to your doctor or pharmacist or nurse before taking Coversyl Arginine:

- 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 have kidney problems or if you are receiving dialysis,
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are to undergo anaesthesia and/or major surgery,
- if you are to undergo 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 have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you have been told by your doctor that you have an intolerance to some sugars,
- if you take aliskiren (medicines used to treat hypertension).

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

Coversyl Arginine is not recommended for use in children and adolescents.

Other medicines and Coversyl Arginine

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

Treatment with Coversyl Arginine can be affected by other medicines. These include:

- other medicines for high blood pressure, including aliskiren, diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs (spironolactone, triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- eplerenone (used to treat heart failure),
- 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 autoimmune 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 Arginine with food and drink

It is preferable to take Coversyl Arginine 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 Arginine 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. Coversyl Arginine 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 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 Arginine 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 Arginine 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.

3. How to take Coversyl Arginine

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 5mg once daily. After one month, this can be increased to 10mg once a day if required. 10mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2.5mg once a day. After a month this can be increased to 5mg once a day and then if necessary to 10mg once daily.

Heart failure: the usual starting dose is 2.5mg once daily. After two weeks, this can be increased to 5mg once a day, which is the maximum recommended dose for heart failure.

Stable coronary artery disease: the usual starting dose is 5mg once daily. After two weeks, this can be increased to 10mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the usual starting dose is 2.5mg once a day. After a week this can be increased to 5mg once a day and after a further week to 10mg once daily.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more Coversyl Arginine 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 Arginine

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Coversyl Arginine, 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

As the treatment with Coversyl Arginine 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:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,

- unusual fast or irregular heart beat or chest pain,
- severe abdominal pain.

In decreasing order of frequency, side effects can include:

- Common (may affect up to 1 in 10 people):**
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, gastrointestinal 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 tiredness.
- Uncommon (may affect up to 1 in 100 people):**
Mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat), intense itching or severe skin rashes, formation of blister clusters over the skin, kidney problems, impotence, sweating, an excess of eosinophils (a type of white blood cells), change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, depression, somnolence, fainting, palpitations, tachycardia, hypoglycaemia (very low blood sugar level) in case of diabetic patients, vasculitis (inflammation of blood vessels), eczema, photosensitivity reaction (increased sensitivity of the skin to sun), arthralgia (joint 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):**
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, cardiovascular disorders (irregular heartbeat, chest pain, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, pancreas (inflammation of the pancreas, which causes severe pain in the abdomen and the back) or liver (hepatitis).

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

Keep out of the sight and reach of children.

Do not take Coversyl Arginine after the expiry date which is printed on the carton and container label. The expiry date refers to the last day of that month.

Keep the container tightly closed in order to protect from moisture.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.

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 you have any unused/left-over medicine, please return this to your pharmacist for safe disposal.

6. Content of the pack and other information

What Coversyl Arginine contains

- The active substance is perindopril arginine. Each film-coated tablet contains 3.395mg of perindopril equivalent to 5mg perindopril arginine.
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica and sodium starch glycolate (type A).
Film-coating: glycerol, hypromellose, copper chlorophyllin, macrogol, magnesium stearate, and titanium dioxide (E171).

What Coversyl Arginine looks like and contents of the pack

Coversyl Arginine are light green, rod-shaped film-coated tablets engraved with the servier logo on one face and plain on the other, scored on both edges.

Coversyl Arginine is available in container packs of 30 tablets.

Manufacturer

Manufactured by: Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France.

Procured from within the EU by the PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/14/3

Leaflet revision & issue date (ref): 31.07.14

Coversyl® is a registered trademark of Biofarma, France.

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- Content of the pack and other information

1. What Coversyl Arginine is and what it is used for

Coversyl Arginine 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 Arginine 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 Arginine

Do not take Coversyl Arginine

- 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 Arginine in early pregnancy – see pregnancy section),
- if you have diabetes mellitus or kidney problems and you are treated with aliskiren.

Warning and precaution

If any of the following apply to you please talk to your doctor or pharmacist or nurse before taking Coversyl Arginine:

- 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 have kidney problems or if you are receiving dialysis,
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are to undergo anaesthesia and/or major surgery,
- if you are to undergo 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 have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you have been told by your doctor that you have an intolerance to some sugars,
- if you take aliskiren (medicines used to treat hypertension).

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

Coversyl Arginine is not recommended for use in children and adolescents.

Other medicines and Coversyl Arginine

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

Treatment with Coversyl Arginine can be affected by other medicines. These include:

- other medicines for high blood pressure, including aliskiren, diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs (spironolactone, triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- eplerenone (used to treat heart failure),
- 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 autoimmune 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 Arginine with food and drink

It is preferable to take Coversyl Arginine 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 Arginine 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. Coversyl Arginine 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 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 Arginine 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 Arginine 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.

3. How to take Coversyl Arginine

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 5mg once daily. After one month, this can be increased to 10mg once a day if required. 10mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2.5mg once a day. After a month this can be increased to 5mg once a day and then if necessary to 10mg once daily.

Heart failure: the usual starting dose is 2.5mg once daily. After two weeks, this can be increased to 5mg once a day, which is the maximum recommended dose for heart failure.

Stable coronary artery disease: the usual starting dose is 5mg once daily. After two weeks, this can be increased to 10mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the usual starting dose is 2.5mg once a day. After a week this can be increased to 5mg once a day and after a further week to 10mg once daily.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more Coversyl Arginine 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 Arginine

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Coversyl Arginine, 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

As the treatment with Coversyl Arginine 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:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,

- unusual fast or irregular heart beat or chest pain,
- severe abdominal pain.

In decreasing order of frequency, side effects can include:

- Common (may affect up to 1 in 10 people):**
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, gastrointestinal 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 tiredness.
- Uncommon (may affect up to 1 in 100 people):**
Mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat), intense itching or severe skin rashes, formation of blister clusters over the skin, kidney problems, impotence, sweating, an excess of eosinophils (a type of white blood cells), change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, depression, somnolence, fainting, palpitations, tachycardia, hypoglycaemia (very low blood sugar level) in case of diabetic patients, vasculitis (inflammation of blood vessels), eczema, photosensitivity reaction (increased sensitivity of the skin to sun), arthralgia (joint 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):**
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, cardiovascular disorders (irregular heartbeat, chest pain, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, pancreas (inflammation of the pancreas, which causes severe pain in the abdomen and the back) or liver (hepatitis).

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

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5. How to store Coversyl Arginine

Keep out of the sight and reach of children.

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Keep the container tightly closed in order to protect from moisture.

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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.

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6. Content of the pack and other information

What Coversyl Arginine contains

- The active substance is perindopril arginine. Each film-coated tablet contains 3.395mg of perindopril equivalent to 5mg perindopril arginine.
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, and sodium starch glycolate (type A).
Film-coating: glycerol, hypromellose, macrogol, magnesium stearate, titanium dioxide (E171), and copper chlorophyllin.

What Coversyl Arginine looks like and contents of the pack

Coversyl Arginine tablets are light green, rod-shaped film-coated tablets engraved with the Servier logo on one face and plain on the other.

Coversyl Arginine is available in container packs of 30 tablets.

Manufactured by: Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy – France.

and
Servier (Ireland) Industries Ltd, Gorey Road, Arklow – Co. Wicklow – Ireland.
Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

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1. What Coversyl Arginine is and what it is used for

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2. What you need to know before you take Coversyl Arginine

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- 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 Arginine in early pregnancy – see pregnancy section),
- if you have diabetes mellitus or kidney problems and you are treated with aliskiren.

Warning and precaution

If any of the following apply to you please talk to your doctor or pharmacist or nurse before taking Coversyl Arginine:

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- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
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- if you are to undergo 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 have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you have been told by your doctor that you have an intolerance to some sugars,
- if you take aliskiren (medicines used to treat hypertension).

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

Coversyl Arginine is not recommended for use in children and adolescents.

Other medicines and Coversyl Arginine

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

Treatment with Coversyl Arginine can be affected by other medicines. These include:

- other medicines for high blood pressure, including aliskiren, diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs (spironolactone, triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- eplerenone (used to treat heart failure),
- 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 autoimmune 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 Arginine with food and drink

It is preferable to take Coversyl Arginine 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 Arginine 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. Coversyl Arginine 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 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 Arginine 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 Arginine 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.

3. How to take Coversyl Arginine

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 5mg once daily. After one month, this can be increased to 10mg once a day if required. 10mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2.5mg once a day. After a month this can be increased to 5mg once a day and then if necessary to 10mg once daily.

Heart failure: the usual starting dose is 2.5mg once daily. After two weeks, this can be increased to 5mg once a day, which is the maximum recommended dose for heart failure.

Stable coronary artery disease: the usual starting dose is 5mg once daily. After two weeks, this can be increased to 10mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the usual starting dose is 2.5mg once a day. After a week this can be increased to 5mg once a day and after a further week to 10mg once daily.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more Coversyl Arginine 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 Arginine

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Coversyl Arginine, 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

As the treatment with Coversyl Arginine 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:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,

- unusual fast or irregular heart beat or chest pain,
- severe abdominal pain.

In decreasing order of frequency, side effects can include:

- Common (may affect up to 1 in 10 people):**
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, gastrointestinal 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 tiredness.
- Uncommon (may affect up to 1 in 100 people):**
Mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat), intense itching or severe skin rashes, formation of blister clusters over the skin, kidney problems, impotence, sweating, an excess of eosinophils (a type of white blood cells), change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, depression, somnolence, fainting, palpitations, tachycardia, hypoglycaemia (very low blood sugar level) in case of diabetic patients, vasculitis (inflammation of blood vessels), eczema, photosensitivity reaction (increased sensitivity of the skin to sun), arthralgia (joint 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):**
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, cardiovascular disorders (irregular heartbeat, chest pain, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, pancreas (inflammation of the pancreas, which causes severe pain in the abdomen and the back) or liver (hepatitis).

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

Keep out of the sight and reach of children.

Do not take Coversyl Arginine after the expiry date which is printed on the carton and container label. The expiry date refers to the last day of that month.

Keep the container tightly closed in order to protect from moisture.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.

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 you have any unused/left-over medicine, please return this to your pharmacist for safe disposal.

6. Content of the pack and other information

What Coversyl Arginine contains

- The active substance is perindopril arginine. Each film-coated tablet contains 3.395mg of perindopril equivalent to 5mg perindopril arginine.
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica, and sodium starch glycolate (type A).
Film-coating: glycerol, hypromellose, macrogol, magnesium stearate, titanium dioxide (E171), and copper chlorophyllin.

What Coversyl Arginine looks like and contents of the pack

Coversyl Arginine tablets are light green, rod-shaped film-coated tablets engraved with the servier logo on one face and plain on the other, scored on both edges.

Coversyl Arginine is available in container packs of 30 tablets.

Manufactured by: Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France or Servier (Ireland) Industries Ltd., Gorey Road, Arklow, Co. Wicklow, Ireland or

EGIS Gyógyszergyár Nyrt, 1106 Budapest, Keresztúri út 30-38, Hungary or

EGIS Gyógyszergyár Nyrt, Lacta Gyógyszergyár, H-9900 Körmend, Mátyás király u. 65, Hungary.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

PPA No: 1151/14/3

Leaflet revision & issue date (ref): 31.07.14

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Coversyl® Arginine 5mg 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is available using the above name, but will be referred to as 'Coversyl Arginine' throughout this leaflet.

What is in this leaflet:

- What Coversyl Arginine is and what it is used for
- What you need to know before you take Coversyl Arginine
- How to take Coversyl Arginine
- Possible side effects
- How to store Coversyl Arginine
- Content of the pack and other information

1. What Coversyl Arginine is and what it is used for

Coversyl Arginine 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 Arginine 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 Arginine

Do not take Coversyl Arginine

- 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 Arginine in early pregnancy – see pregnancy section),
- if you have diabetes mellitus or kidney problems and you are treated with aliskiren.

Warning and precaution

If any of the following apply to you please talk to your doctor or pharmacist or nurse before taking Coversyl Arginine:

- 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 have kidney problems or if you are receiving dialysis,
- if you suffer from a collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
- if you have diabetes,
- if you are on a salt restricted diet or use salt substitutes which contain potassium,
- if you are to undergo anaesthesia and/or major surgery,
- if you are to undergo 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 have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you have been told by your doctor that you have an intolerance to some sugars,
- if you take aliskiren (medicines used to treat hypertension).

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

Coversyl Arginine is not recommended for use in children and adolescents.

Other medicines and Coversyl Arginine

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

Treatment with Coversyl Arginine can be affected by other medicines. These include:

- other medicines for high blood pressure, including aliskiren, diuretics (medicines which increase the amount of urine produced by the kidneys),
- potassium-sparing drugs (spironolactone, triamterene, amiloride), potassium supplements or potassium-containing salt substitutes,
- eplerenone (used to treat heart failure),
- 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 autoimmune 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 Arginine with food and drink

It is preferable to take Coversyl Arginine 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 Arginine 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. Coversyl Arginine 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 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 Arginine 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 Arginine 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.

3. How to take Coversyl Arginine

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 5mg once daily. After one month, this can be increased to 10mg once a day if required. 10mg a day is the maximum recommended dose for high blood pressure.

If you are 65 or older, the usual starting dose is 2.5mg once a day. After a month this can be increased to 5mg once a day and then if necessary to 10mg once daily.

Heart failure: the usual starting dose is 2.5mg once daily. After two weeks, this can be increased to 5mg once a day, which is the maximum recommended dose for heart failure.

Stable coronary artery disease: the usual starting dose is 5mg once daily. After two weeks, this can be increased to 10mg once daily, which is the maximum recommended dose in this indication.

If you are 65 or older, the usual starting dose is 2.5mg once a day. After a week this can be increased to 5mg once a day and after a further week to 10mg once daily.

Use in children and adolescents

Use in children and adolescents is not recommended.

If you take more Coversyl Arginine 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 Arginine

It is important to take your medicine every day as regular treatment works better. However, if you forget to take a dose of Coversyl Arginine, 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

As the treatment with Coversyl Arginine 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:

- swelling of the face, lips, mouth, tongue or throat, difficulty in breathing,
- severe dizziness or fainting,

- unusual fast or irregular heart beat or chest pain,
- severe abdominal pain.

In decreasing order of frequency, side effects can include:

- Common (may affect up to 1 in 10 people):**
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, gastrointestinal 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 tiredness.
- Uncommon (may affect up to 1 in 100 people):**
Mood swings, sleep disturbances, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face, tongue or throat), intense itching or severe skin rashes, formation of blister clusters over the skin, kidney problems, impotence, sweating, an excess of eosinophils (a type of white blood cells), change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, depression, somnolence, fainting, palpitations, tachycardia, hypoglycaemia (very low blood sugar level) in case of diabetic patients, vasculitis (inflammation of blood vessels), eczema, photosensitivity reaction (increased sensitivity of the skin to sun), arthralgia (joint 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):**
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, cardiovascular disorders (irregular heartbeat, chest pain, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), rhinitis (blocked up or runny nose), erythema multiforme, changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets, pancreas (inflammation of the pancreas, which causes severe pain in the abdomen and the back) or liver (hepatitis).

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

Keep out of the sight and reach of children.

Do not take Coversyl Arginine after the expiry date which is printed on the carton and container label. The expiry date refers to the last day of that month.

Keep the container tightly closed in order to protect from moisture.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.

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 you have any unused/left-over medicine, please return this to your pharmacist for safe disposal.

6. Content of the pack and other information

What Coversyl Arginine contains

- The active substance is perindopril arginine. Each film-coated tablet contains 3.395mg of perindopril equivalent to 5mg perindopril arginine.
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maltodextrin, hydrophobic colloidal silica and sodium starch glycolate (type A).
Film-coating: glycerol, hypromellose, macrogol, magnesium stearate, titanium dioxide (E171) and copper chlorophyllin.

What Coversyl Arginine looks like and contents of the pack

Coversyl Arginine tablets are light green, rod-shaped film-coated tablets engraved with the Servier logo on one face and plain on the other.

Coversyl Arginine is available in container packs of 30 tablets.

Manufactured by:

ANPHARM Przedsiębiorstwo Farmaceutyczne S.A., Ul. Annopol 6B, 03-236 Warszawa, Poland

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

PPA No: 1151/14/3

Leaflet revision & issue date (ref): 31.07.14

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