

Package leaflet - information for the user

Acerycal® 5mg/5mg tablets

Acerycal® 5mg/10mg tablets

Acerycal® 10mg/5mg tablets

Acerycal® 10mg/10mg tablets

Perindopril arginine/amlodipine

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

In this leaflet:

1. What ACERYCAL is and what it is used for

2. What you need to know before you take ACERYCAL

3. How to take ACERYCAL

4. Possible side effects

5. How to store ACERYCAL

6. Further information

1 . WHAT ACERYCAL IS AND WHAT IT IS USED FOR

ACERYCAL is prescribed for treatment of high blood pressure (hypertension) and/or treatment of stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked).

Patients already taking perindopril and Amlodipine from separate tablets may instead receive one tablet of ACERYCAL which contains both ingredients.

ACERYCAL is a combination of two active ingredients, perindopril and Amlodipine. Perindopril is an ACE (angiotension converting enzyme) inhibitor. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Together they work to widen and relax the blood vessels so that blood passes through them more easily and makes it easier for your heart to maintain a good blood flow.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACERYCAL

Do not take ACERYCAL

- if you are allergic (hypersensitive) to perindopril or any other ACE inhibitor, or to Amlodipine or any other calcium antagonists, or any of the other ingredients of ACERYCAL,
- if you are more than 3 months pregnant. (it is also better to avoid ACERYCAL in early pregnancy – see pregnancy section),
- 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 a narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- if you have severe low blood pressure (hypotension),
- if you suffer from heart failure after a heart attack

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Acerycal.

If you have any of the following please talk to your doctor before taking Acerycal:

- hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery which supplies the kidney with blood),
 - heart failure,
 - severe increase in blood pressure (hypertensive crisis),
 - any other heart problems,
 - liver problems,
 - kidney problems or if you are receiving dialysis,
 - collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
 - diabetes,
 - if you are on a salt restricted diet or use salt substitutes which contain potassium (a well balanced potassium blood level is essential).
 - if you are elderly and your dose needs to be increased.
 - 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 Acerycal”.

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

ACERYCAL 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).

When you are taking ACERYCAL, you should also inform your doctor or the medical staff if you:

- are going to have a general anaesthetic and/or major surgery,
- have recently suffered from diarrhoea or vomiting (being sick),
- are to undergo LDL apheresis (the removal of cholesterol from your blood by a machine),
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

ACERYCAL is not recommended for use in children and adolescents.

Other medicines and Acerycal

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

You should avoid ACERYCAL with:

- lithium (used to treat mania or depression),
- Estramustine (used in cancer therapy),
- potassium-sparing diuretics (spironolactone, triamterene), potassium supplements or potassium-containing salt substitutes.

Treatment with ACERYCAL 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 high blood pressure: if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Acerycal” and “Warnings and precautions”), or diuretics (medicines which increase the amount of urine produced by the kidneys),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, neuroleptics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that widen the blood vessels),
- heparin (medicines used to thin blood),
- ephedrine, noradrenaline or adrenaline (medicines used to treat low blood pressure, shock or asthma),
- baclofen or dantrolene (infusion) both used to treat muscle stiffness in diseases such as multiple sclerosis; dantrolene is also used to treat malignant hyperthermia during anaesthesia (symptoms including very high fever and muscle stiffness),
- some antibiotics such as rifampicin, erythromycin, clarithromycin,
- antiepileptic agents such as carbamazepine, Phenobarbital, phenytoin, fosphenytoin, primidone,
- itraconazole, ketoconazole (medicines used for treatment of fungal infections),
- alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin,
- amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer),
- corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV).

Taking ACERYCAL with food and drink

ACERYCAL should be taken before a meal.

Grapefruit juice and grapefruit should not be consumed by people who are taking ACERYCAL. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of ACERYCAL.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 ACERYCAL before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of ACERYCAL. ACERYCAL 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. ACERYCAL 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

ACERYCAL may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy, weak or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Important information about some of the ingredients of ACERYCAL

ACERYCAL contains lactose monohydrate (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 ACERYCAL

Always take ACERYCAL exactly as your doctor has told you. You should 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. This will normally be one tablet per day.

ACERYCAL will usually be prescribed for patients already taking perindopril and Amlodipine from separate tablets.

If you take more ACERYCAL 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 your legs raised can help.

If you forget to take ACERYCAL

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

As the treatment with ACERYCAL is usually life-long, you should discuss with your doctor before you stop taking your tablets. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 .POSSIBLE SIDE EFFECTS

Like all medicines, ACERYCAL 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**:

- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing,
- swelling of eyelids, face or lips,
- swelling of the tongue and throat, which causes great difficulty breathing,
- severe skin reactions including 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,
- severe dizziness or fainting,
- heart attack, unusual fast or abnormal heart beat.
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following **common side effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

- Common side effects (occur in less than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, sleepiness (especially at the beginning of treatment), vertigo, numbness or tingling sensation in your limbs, vision disturbances (including double vision), tinnitus (sensation of noises in the ears), palpitations (awareness of your heartbeat), flushing, light-headedness due to low blood pressure, cough, shortness of breath, nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation, allergic reactions (such as skin rashes, itching), muscle cramps, tiredness, weakness, ankle swelling (oedema).

Other side effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- Uncommon side effects (occur in less than 1 in 100 users but in more than 1 in 1000 users): mood swings, anxiety, depression, sleeplessness, sleep disturbances, trembling, fainting, loss of pain sensation, rhinitis (blocked up or runny nose), altered bowel habits, hair loss, red patches on skin, skin discoloration, back pain, muscle or joint pain, chest pain, disorder in passing urine, increased need to urinate at night, increased number of times passing urine, pain, feeling unwell, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face or tongue), kidney problems, impotence, increased sweating, discomfort or enlargement of the breasts in men, weight increase or decrease,
- Rare side effects (occur in less than 1 in 1000 users but in more than 1 in 10,000 users): confusion.
- Very rare side effects (occur in less than 1 in 10,000 users): cardiovascular disorders (irregular heartbeat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), swelling of eyelids, face or lips, swelling of the tongue and throat, which causes great difficulty in breathing, severe skin reactions including 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), erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), sensitivity to light, disorders of the blood, inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell, abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests, abdominal bloating (gastritis), disorder of the nerves which can cause weakness, tingling or numbness, increased muscle tension, vasculitis (inflammation of blood vessels), swelling of the gums, excess sugar in blood (hyperglycaemia).
- The following side effects have also been reported by patients taking ACERYCAL: hypoglycaemia (very low blood sugar level), disorders combining rigidity, tremor, and/or movement disorders.

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 HPRC 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 ACERYCAL

Keep out of the reach and sight of children.

Do not use ACERYCAL after the expiry date which is stated on the carton and bottle.- The expiry date refers to the last day of that month. Keep the bottle tightly closed in order to protect from moisture. Store in the original package.

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 ACERYCAL contains

- The active substances are perindopril arginine and Amlodipine. ACERYCAL 5mg/5mg: one tablet contains 5mg perindopril arginine and 5mg Amlodipine. ACERYCAL 10mg/5mg: one tablet contains 10mg perindopril arginine and 5mg Amlodipine.

ACERYCAL 5mg/10mg: one tablet contains 5mg perindopril arginine and 10mg Amlodipine.

ACERYCAL 10mg/10mg: one tablet contains 10mg perindopril arginine and 10mg Amlodipine.

- The other ingredients in the tablet are: lactose monohydrate, magnesium stearate, cellulose microcrystalline, colloidal anhydrous silica.

What ACERYCAL looks like and contents of the pack

ACERYCAL 5mg/5mg tablets are white, rod-shaped tablets engraved with 5/5 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 5mg/5mg' in its source country.

ACERYCAL 10mg/5mg tablets are white, triangular-shaped tablets engraved with 10/5 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 10mg/5mg' in its source country.

ACERYCAL 5mg/10mg tablets are white, square-shaped tablets engraved with 5/10 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 5mg/10mg' in its source country.

ACERYCAL 10mg/10mg tablets are white, round tablets engraved with 10/10 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 10mg/10mg' in its source country.

The tablets are supplied in containers of 30 tablets.

Parallel Product Authorisation Holder and Manufacturer

Parallel Product Authorisation holder:

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

Manufacturer: Servier (Ireland) Industries Ltd Gorey Road Arklow -Co. Wicklow – Ireland or Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France or Anpharm Przedsiębiorstwo Farmaceutyczne S.A., Ul. Annapol 6B, 03-236 Warsaw, Poland.

This medicine has been repackaged by

Cast Healthcare Ltd,
Unit B6 The Business Centre,
5-7 Tobermore Road,
Draperstown, Northern Ireland,
BT45 7AG, UK

This medicine has been imported from Hungary. In Hungary the name of the medicine is COVERCARD.

ACERYCAL is a registered trademark of BIOFARMA|

Belgium	COVERAM
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Czech Republic	PRESTANCE
Denmark	COVERSICAL
Estonia	COVERAM
Finland	COVERAM
France	COVERAM
Hungary	ARMIXXAM
Iceland	COVERSICAL
Ireland	ACERYCAL
Italy	COVERLAM
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Lithuania	PRESTERAM
Luxembourg	COVERAM
Malta	COVERAM
Netherlands	COVERAM arg
Poland	Co-Prestarium
Portugal	COVERAM
Romania	PRESTANCE
Slovakia	PRESTANCE
Slovenia	PRESTANCE
Spain	COVERLAM
United Kingdom	ACERYCAL

This leaflet was last approved in March 2016

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Perindopril arginine/amlodipine

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-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 get 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 ACERYCAL IS AND WHAT IT IS USED FOR

ACERYCAL is prescribed for treatment of high blood pressure (hypertension) and/or treatment of stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked).

Patients already taking perindopril and Amlodipine from separate tablets may instead receive one tablet of ACERYCAL which contains both ingredients.

ACERYCAL is a combination of two active ingredients, perindopril and Amlodipine. Perindopril is an ACE (angiotension converting enzyme) inhibitor. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Together they work to widen and relax the blood vessels so that blood passes through them more easily and makes it easier for your heart to maintain a good blood flow.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACERYCAL

Do not take ACERYCAL

- if you are allergic (hypersensitive) to perindopril or any other ACE inhibitor, or to Amlodipine or any other calcium antagonists, or any of the other ingredients of ACERYCAL,
- if you are more than 3 months pregnant. (it is also better to avoid ACERYCAL in early pregnancy – see pregnancy section),
- 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 a narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- if you have severe low blood pressure (hypotension),
- if you suffer from heart failure after a heart attack

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Acerycal.

If you have any of the following please talk to your doctor before taking Acerycal:

- hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery which supplies the kidney with blood),
 - heart failure,
 - severe increase in blood pressure (hypertensive crisis),
 - any other heart problems,
 - liver problems,
 - kidney problems or if you are receiving dialysis,
 - collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
 - diabetes,
 - if you are on a salt restricted diet or use salt substitutes which contain potassium (a well balanced potassium blood level is essential).
 - if you are elderly and your dose needs to be increased.
 - 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 Acerycal”.

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

ACERYCAL 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).

When you are taking ACERYCAL, you should also inform your doctor or the medical staff if you:

- are going to have a general anaesthetic and/or major surgery,
- have recently suffered from diarrhoea or vomiting (being sick),
- are to undergo LDL apheresis (the removal of cholesterol from your blood by a machine),
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

ACERYCAL is not recommended for use in children and adolescents.

Other medicines and Acerycal

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

You should avoid ACERYCAL with:

- lithium (used to treat mania or depression),
- Estramustine (used in cancer therapy),
- potassium-sparing diuretics (spironolactone, triamterene), potassium supplements or potassium-containing salt substitutes.

Treatment with ACERYCAL 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 high blood pressure: if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Acerycal” and “Warnings and precautions”), or diuretics (medicines which increase the amount of urine produced by the kidneys),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, neuroleptics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that widen the blood vessels),
- heparin (medicines used to thin blood),
- ephedrine, noradrenaline or adrenaline (medicines used to treat low blood pressure, shock or asthma),
- baclofen or dantrolene (infusion) both used to treat muscle stiffness in diseases such as multiple sclerosis; dantrolene is also used to treat malignant hyperthermia during anaesthesia (symptoms including very high fever and muscle stiffness),
- some antibiotics such as rifampicin, erythromycin, clarithromycin,
- antiepileptic agents such as carbamazepine, Phenobarbital, phenytoin, fosphenytoin, primidone,
- itraconazole, ketoconazole (medicines used for treatment of fungal infections),
- alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin,
- amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer),
- corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV).

Taking ACERYCAL with food and drink

ACERYCAL should be taken before a meal.

Grapefruit juice and grapefruit should not be consumed by people who are taking ACERYCAL. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of ACERYCAL.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 ACERYCAL before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of ACERYCAL. ACERYCAL 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. ACERYCAL 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

ACERYCAL may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy, weak or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Important information about some of the ingredients of ACERYCAL

ACERYCAL contains lactose monohydrate (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 ACERYCAL

Always take ACERYCAL exactly as your doctor has told you. You should 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. This will normally be one tablet per day.

ACERYCAL will usually be prescribed for patients already taking perindopril and Amlodipine from separate tablets.

If you take more ACERYCAL 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 your legs raised can help.

If you forget to take ACERYCAL

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

As the treatment with ACERYCAL is usually life-long, you should discuss with your doctor before you stop taking your tablets. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 .POSSIBLE SIDE EFFECTS

Like all medicines, ACERYCAL 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**:

- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing,
- swelling of eyelids, face or lips,
- swelling of the tongue and throat, which causes great difficulty breathing,
- severe skin reactions including 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,
- severe dizziness or fainting,
- heart attack, unusual fast or abnormal heart beat.
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following **common side effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

- Common side effects (occur in less than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, sleepiness (especially at the beginning of treatment), vertigo, numbness or tingling sensation in your limbs, vision disturbances (including double vision), tinnitus (sensation of noises in the ears), palpitations (awareness of your heartbeat), flushing, light-headedness due to low blood pressure, cough, shortness of breath, nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation, allergic reactions (such as skin rashes, itching), muscle cramps, tiredness, weakness, ankle swelling (oedema).

Other side effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- Uncommon side effects (occur in less than 1 in 100 users but in more than 1 in 1000 users): mood swings, anxiety, depression, sleeplessness, sleep disturbances, trembling, fainting, loss of pain sensation, rhinitis (blocked up or runny nose), altered bowel habits, hair loss, red patches on skin, skin discoloration, back pain, muscle or joint pain, chest pain, disorder in passing urine, increased need to urinate at night, increased number of times passing urine, pain, feeling unwell, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face or tongue), kidney problems, impotence, increased sweating, discomfort or enlargement of the breasts in men, weight increase or decrease,
- Rare side effects (occur in less than 1 in 1000 users but in more than 1 in 10,000 users): confusion.
- Very rare side effects (occur in less than 1 in 10,000 users): cardiovascular disorders (irregular heartbeat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), swelling of eyelids, face or lips, swelling of the tongue and throat, which causes great difficulty in breathing, severe skin reactions including 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), erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), sensitivity to light, disorders of the blood, inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell, abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests, abdominal bloating (gastritis), disorder of the nerves which can cause weakness, tingling or numbness, increased muscle tension, vasculitis (inflammation of blood vessels), swelling of the gums, excess sugar in blood (hyperglycaemia).
- The following side effects have also been reported by patients taking ACERYCAL: hypoglycaemia (very low blood sugar level), disorders combining rigidity, tremor, and/or movement disorders.

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 ACERYCAL

Keep out of the reach and sight of children.

Do not use ACERYCAL after the expiry date which is stated on the carton and bottle.- The expiry date refers to the last day of that month. Keep the bottle tightly closed in order to protect from moisture. Store in the original package.

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 ACERYCAL contains

- The active substances are perindopril arginine and Amlodipine. ACERYCAL 5mg/5mg: one tablet contains 5mg perindopril arginine and 5mg Amlodipine. ACERYCAL 10mg/5mg: one tablet contains 10mg perindopril arginine and 5mg Amlodipine.

ACERYCAL 5mg/10mg: one tablet contains 5mg perindopril arginine and 10mg Amlodipine.

ACERYCAL 10mg/10mg: one tablet contains 10mg perindopril arginine and 10mg Amlodipine.

- The other ingredients in the tablet are: lactose monohydrate, magnesium stearate, cellulose microcrystalline, colloidal anhydrous silica.

What ACERYCAL looks like and contents of the pack

ACERYCAL 5mg/5mg tablets are white, rod-shaped tablets engraved with 5/5 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 5mg/5mg' in its source country.

ACERYCAL 10mg/5mg tablets are white, triangular-shaped tablets engraved with 10/5 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 10mg/5mg' in its source country.

ACERYCAL 5mg/10mg tablets are white, square-shaped tablets engraved with 5/10 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 5mg/10mg' in its source country.

ACERYCAL 10mg/10mg tablets are white, round tablets engraved with 10/10 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 10mg/10mg' in its source country.

The tablets are supplied in containers of 30 tablets.

Parallel Product Authorisation Holder and Manufacturer

Parallel Product Authorisation holder:

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

Manufacturer: Servier (Ireland) Industries Ltd Gorey Road Arklow -Co. Wicklow – Ireland or Les Laboratoires Servier Industrie, 905 route de Saran, 45520 Gidy, France or Anpharm Przedsiębiorstwo Farmaceutyczne S.A., Ul. Annapol 6B, 03-236 Warsaw, Poland.

This medicine has been repackaged by

IMED Pharma Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

This medicine has been imported from Hungary. In Hungary the name of the medicine is COVERCARD.

ACERYCAL is a registered trademark of BIOFARMA|

Belgium	COVERAM
Bulgaria	PRESTARUM-CO
Cyprus	COVERAM
Czech Republic	PRESTANCE
Denmark	COVERSICAL
Estonia	COVERAM
Finland	COVERAM
France	COVERAM
Hungary	ARMIXXAM
Iceland	COVERSICAL
Ireland	ACERYCAL
Italy	COVERLAM
Latvia	PRESTERAM
Lithuania	PRESTERAM
Luxembourg	COVERAM
Malta	COVERAM
Netherlands	COVERAM arg
Poland	Co-Prestarium
Portugal	COVERAM
Romania	PRESTANCE
Slovakia	PRESTANCE
Slovenia	PRESTANCE
Spain	COVERLAM
United Kingdom	ACERYCAL

This leaflet was last approved in March 2016

Package leaflet - information for the user

Acerycal® 5mg/5mg tablets

Acerycal® 5mg/10mg tablets

Acerycal® 10mg/5mg tablets

Acerycal® 10mg/10mg tablets

Perindopril arginine/amlodipine

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

In this leaflet:

1. What ACERYCAL is and what it is used for

2. What you need to know before you take ACERYCAL

3. How to take ACERYCAL

4. Possible side effects

5. How to store ACERYCAL

6. Further information

1 . WHAT ACERYCAL IS AND WHAT IT IS USED FOR

ACERYCAL is prescribed for treatment of high blood pressure (hypertension) and/or treatment of stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked).

Patients already taking perindopril and Amlodipine from separate tablets may instead receive one tablet of ACERYCAL which contains both ingredients.

ACERYCAL is a combination of two active ingredients, perindopril and Amlodipine. Perindopril is an ACE (angiotension converting enzyme) inhibitor. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Together they work to widen and relax the blood vessels so that blood passes through them more easily and makes it easier for your heart to maintain a good blood flow.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACERYCAL

Do not take ACERYCAL

- if you are allergic (hypersensitive) to perindopril or any other ACE inhibitor, or to Amlodipine or any other calcium antagonists, or any of the other ingredients of ACERYCAL,
- if you are more than 3 months pregnant. (it is also better to avoid ACERYCAL in early pregnancy – see pregnancy section),
- 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 a narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- if you have severe low blood pressure (hypotension),
- if you suffer from heart failure after a heart attack

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Acerycal.

If you have any of the following please talk to your doctor before taking Acerycal:

- hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery which supplies the kidney with blood),
 - heart failure,
 - severe increase in blood pressure (hypertensive crisis),
 - any other heart problems,
 - liver problems,
 - kidney problems or if you are receiving dialysis,
 - collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
 - diabetes,
 - if you are on a salt restricted diet or use salt substitutes which contain potassium (a well balanced potassium blood level is essential).
 - if you are elderly and your dose needs to be increased.
 - 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 Acerycal”.

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

ACERYCAL 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).

When you are taking ACERYCAL, you should also inform your doctor or the medical staff if you:

- are going to have a general anaesthetic and/or major surgery,
- have recently suffered from diarrhoea or vomiting (being sick),
- are to undergo LDL apheresis (the removal of cholesterol from your blood by a machine),
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

ACERYCAL is not recommended for use in children and adolescents.

Other medicines and Acerycal

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

You should avoid ACERYCAL with:

- lithium (used to treat mania or depression),
- Estramustine (used in cancer therapy),
- potassium-sparing diuretics (spironolactone, triamterene), potassium supplements or potassium-containing salt substitutes.

Treatment with ACERYCAL 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 high blood pressure: if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Acerycal” and “Warnings and precautions”), or diuretics (medicines which increase the amount of urine produced by the kidneys),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, neuroleptics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that widen the blood vessels),
- heparin (medicines used to thin blood),
- ephedrine, noradrenaline or adrenaline (medicines used to treat low blood pressure, shock or asthma),
- baclofen or dantrolene (infusion) both used to treat muscle stiffness in diseases such as multiple sclerosis; dantrolene is also used to treat malignant hyperthermia during anaesthesia (symptoms including very high fever and muscle stiffness),
- some antibiotics such as rifampicin, erythromycin, clarithromycin,
- antiepileptic agents such as carbamazepine, Phenobarbital, phenytoin, fosphenytoin, primidone,
- itraconazole, ketoconazole (medicines used for treatment of fungal infections),
- alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin,
- amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer),
- corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV).

Taking ACERYCAL with food and drink

ACERYCAL should be taken before a meal.

Grapefruit juice and grapefruit should not be consumed by people who are taking ACERYCAL. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of ACERYCAL.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 ACERYCAL before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of ACERYCAL. ACERYCAL 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. ACERYCAL 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

ACERYCAL may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy, weak or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Important information about some of the ingredients of ACERYCAL

ACERYCAL contains lactose monohydrate (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 ACERYCAL

Always take ACERYCAL exactly as your doctor has told you. You should 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. This will normally be one tablet per day.

ACERYCAL will usually be prescribed for patients already taking perindopril and Amlodipine from separate tablets.

If you take more ACERYCAL 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 your legs raised can help.

If you forget to take ACERYCAL

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

As the treatment with ACERYCAL is usually life-long, you should discuss with your doctor before you stop taking your tablets. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 .POSSIBLE SIDE EFFECTS

Like all medicines, ACERYCAL 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**:

- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing,
- swelling of eyelids, face or lips,
- swelling of the tongue and throat, which causes great difficulty breathing,
- severe skin reactions including 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,
- severe dizziness or fainting,
- heart attack, unusual fast or abnormal heart beat.
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following **common side effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

- Common side effects (occur in less than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, sleepiness (especially at the beginning of treatment), vertigo, numbness or tingling sensation in your limbs, vision disturbances (including double vision), tinnitus (sensation of noises in the ears), palpitations (awareness of your heartbeat), flushing, light-headedness due to low blood pressure, cough, shortness of breath, nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation, allergic reactions (such as skin rashes, itching), muscle cramps, tiredness, weakness, ankle swelling (oedema).

Other side effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- Uncommon side effects (occur in less than 1 in 100 users but in more than 1 in 1000 users): mood swings, anxiety, depression, sleeplessness, sleep disturbances, trembling, fainting, loss of pain sensation, rhinitis (blocked up or runny nose), altered bowel habits, hair loss, red patches on skin, skin discoloration, back pain, muscle or joint pain, chest pain, disorder in passing urine, increased need to urinate at night, increased number of times passing urine, pain, feeling unwell, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face or tongue), kidney problems, impotence, increased sweating, discomfort or enlargement of the breasts in men, weight increase or decrease,
- Rare side effects (occur in less than 1 in 1000 users but in more than 1 in 10,000 users): confusion.
- Very rare side effects (occur in less than 1 in 10,000 users): cardiovascular disorders (irregular heartbeat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), swelling of eyelids, face or lips, swelling of the tongue and throat, which causes great difficulty in breathing, severe skin reactions including 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), erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), sensitivity to light, disorders of the blood, inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell, abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests, abdominal bloating (gastritis), disorder of the nerves which can cause weakness, tingling or numbness, increased muscle tension, vasculitis (inflammation of blood vessels), swelling of the gums, excess sugar in blood (hyperglycaemia).
- The following side effects have also been reported by patients taking ACERYCAL: hypoglycaemia (very low blood sugar level), disorders combining rigidity, tremor, and/or movement disorders.

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 ACERYCAL

Keep out of the reach and sight of children.

Do not use ACERYCAL after the expiry date which is stated on the carton and bottle.- The expiry date refers to the last day of that month. Keep the bottle tightly closed in order to protect from moisture. Store in the original package.

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 ACERYCAL contains

- The active substances are perindopril arginine and Amlodipine. ACERYCAL 5mg/5mg: one tablet contains 5mg perindopril arginine and 5mg Amlodipine. ACERYCAL 10mg/5mg: one tablet contains 10mg perindopril arginine and 5mg Amlodipine.

ACERYCAL 5mg/10mg: one tablet contains 5mg perindopril arginine and 10mg Amlodipine.

ACERYCAL 10mg/10mg: one tablet contains 10mg perindopril arginine and 10mg Amlodipine.

- The other ingredients in the tablet are: lactose monohydrate, magnesium stearate, cellulose microcrystalline, colloidal anhydrous silica.

What ACERYCAL looks like and contents of the pack

ACERYCAL 5mg/5mg tablets are white, rod-shaped tablets engraved with 5/5 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 5mg/5mg' in its source country.

ACERYCAL 10mg/5mg tablets are white, triangular-shaped tablets engraved with 10/5 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 10mg/5mg' in its source country.

ACERYCAL 5mg/10mg tablets are white, square-shaped tablets engraved with 5/10 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 5mg/10mg' in its source country.

ACERYCAL 10mg/10mg tablets are white, round tablets engraved with 10/10 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 10mg/10mg' in its source country.

The tablets are supplied in containers of 30 tablets.

Product procured from within the EU by the Parallel Product Authorisation Holder:

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

Manufacturer

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

Repackaged by:

Cast Healthcare Ltd,
Unit B6 The Business Centre,
5-7 Tobermore Road,
Draperstown, Northern Ireland,
BT45 7AG, UK

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

Belgium	COVERAM
Bulgaria	PRESTARUM-CO
Cyprus	COVERAM
Czech Republic	PRESTANCE
Denmark	COVERSICAL
Estonia	COVERAM
Finland	COVERAM
France	COVERAM
Hungary	ARMIXXAM
Iceland	COVERSICAL
Ireland	ACERYCAL
Italy	COVERLAM
Latvia	PRESTERAM
Lithuania	PRESTERAM
Luxembourg	COVERAM
Malta	COVERAM
Netherlands	COVERAM arg
Poland	Co-Prestarium
Portugal	COVERAM
Romania	PRESTANCE
Slovakia	PRESTANCE
Slovenia	PRESTANCE
Spain	COVERLAM
United Kingdom	ACERYCAL

This leaflet was last approved in March 2016

Package leaflet - information for the user

Acerycal® 5mg/5mg tablets

Acerycal® 5mg/10mg tablets

Acerycal® 10mg/5mg tablets

Acerycal® 10mg/10mg tablets

Perindopril arginine/amlodipine

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

In this leaflet:

1. What ACERYCAL is and what it is used for

2. What you need to know before you take ACERYCAL

3. How to take ACERYCAL

4. Possible side effects

5. How to store ACERYCAL

6. Further information

1 . WHAT ACERYCAL IS AND WHAT IT IS USED FOR

ACERYCAL is prescribed for treatment of high blood pressure (hypertension) and/or treatment of stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked).

Patients already taking perindopril and Amlodipine from separate tablets may instead receive one tablet of ACERYCAL which contains both ingredients.

ACERYCAL is a combination of two active ingredients, perindopril and Amlodipine. Perindopril is an ACE (angiotension converting enzyme) inhibitor. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Together they work to widen and relax the blood vessels so that blood passes through them more easily and makes it easier for your heart to maintain a good blood flow.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACERYCAL

Do not take ACERYCAL

- if you are allergic (hypersensitive) to perindopril or any other ACE inhibitor, or to Amlodipine or any other calcium antagonists, or any of the other ingredients of ACERYCAL,
- if you are more than 3 months pregnant. (it is also better to avoid ACERYCAL in early pregnancy – see pregnancy section),
- 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 a narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body)
- if you have severe low blood pressure (hypotension),
- if you suffer from heart failure after a heart attack

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Acerycal.

If you have any of the following please talk to your doctor before taking Acerycal:

- hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery which supplies the kidney with blood),
 - heart failure,
 - severe increase in blood pressure (hypertensive crisis),
 - any other heart problems,
 - liver problems,
 - kidney problems or if you are receiving dialysis,
 - collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma,
 - diabetes,
 - if you are on a salt restricted diet or use salt substitutes which contain potassium (a well balanced potassium blood level is essential).
 - if you are elderly and your dose needs to be increased.
 - 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 Acerycal”.

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

ACERYCAL 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).

When you are taking ACERYCAL, you should also inform your doctor or the medical staff if you:

- are going to have a general anaesthetic and/or major surgery,
- have recently suffered from diarrhoea or vomiting (being sick),
- are to undergo LDL apheresis (the removal of cholesterol from your blood by a machine),
- are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings.

ACERYCAL is not recommended for use in children and adolescents.

Other medicines and Acerycal

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

You should avoid ACERYCAL with:

- lithium (used to treat mania or depression),
- Estramustine (used in cancer therapy),
- potassium-sparing diuretics (spironolactone, triamterene), potassium supplements or potassium-containing salt substitutes.

Treatment with ACERYCAL 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 high blood pressure: if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Acerycal” and “Warnings and precautions”), or diuretics (medicines which increase the amount of urine produced by the kidneys),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or high dose aspirin,
- medicines to treat diabetes (such as insulin),
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, neuroleptics),
- immunosuppressants (medicines which reduce the defence mechanism of the body) used for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin),
- allopurinol (for the treatment of gout),
- procainamide (for the treatment of an irregular heart beat),
- vasodilators including nitrates (products that widen the blood vessels),
- heparin (medicines used to thin blood),
- ephedrine, noradrenaline or adrenaline (medicines used to treat low blood pressure, shock or asthma),
- baclofen or dantrolene (infusion) both used to treat muscle stiffness in diseases such as multiple sclerosis; dantrolene is also used to treat malignant hyperthermia during anaesthesia (symptoms including very high fever and muscle stiffness),
- some antibiotics such as rifampicin, erythromycin, clarithromycin,
- antiepileptic agents such as carbamazepine, Phenobarbital, phenytoin, fosphenytoin, primidone,
- itraconazole, ketoconazole (medicines used for treatment of fungal infections),
- alpha-blockers used for the treatment of enlarged prostate such as prazosin, alfuzosin, doxazosin, tamsulosin, terazosin,
- amifostine (used to prevent or reduce side effects caused by other medicines or radiation therapy that are used to treat cancer),
- corticosteroids (used to treat various conditions including severe asthma and rheumatoid arthritis),
- gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis).
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV).

Taking ACERYCAL with food and drink

ACERYCAL should be taken before a meal.

Grapefruit juice and grapefruit should not be consumed by people who are taking ACERYCAL. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of ACERYCAL.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 ACERYCAL before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of ACERYCAL. ACERYCAL 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. ACERYCAL 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

ACERYCAL may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy, weak or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Important information about some of the ingredients of ACERYCAL

ACERYCAL contains lactose monohydrate (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 ACERYCAL

Always take ACERYCAL exactly as your doctor has told you. You should 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. This will normally be one tablet per day.

ACERYCAL will usually be prescribed for patients already taking perindopril and Amlodipine from separate tablets.

If you take more ACERYCAL 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 your legs raised can help.

If you forget to take ACERYCAL

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

As the treatment with ACERYCAL is usually life-long, you should discuss with your doctor before you stop taking your tablets. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 .POSSIBLE SIDE EFFECTS

Like all medicines, ACERYCAL 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**:

- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing,
- swelling of eyelids, face or lips,
- swelling of the tongue and throat, which causes great difficulty breathing,
- severe skin reactions including 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,
- severe dizziness or fainting,
- heart attack, unusual fast or abnormal heart beat.
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following **common side effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

- Common side effects (occur in less than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, sleepiness (especially at the beginning of treatment), vertigo, numbness or tingling sensation in your limbs, vision disturbances (including double vision), tinnitus (sensation of noises in the ears), palpitations (awareness of your heartbeat), flushing, light-headedness due to low blood pressure, cough, shortness of breath, nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation, allergic reactions (such as skin rashes, itching), muscle cramps, tiredness, weakness, ankle swelling (oedema).

Other side effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- Uncommon side effects (occur in less than 1 in 100 users but in more than 1 in 1000 users): mood swings, anxiety, depression, sleeplessness, sleep disturbances, trembling, fainting, loss of pain sensation, rhinitis (blocked up or runny nose), altered bowel habits, hair loss, red patches on skin, skin discoloration, back pain, muscle or joint pain, chest pain, disorder in passing urine, increased need to urinate at night, increased number of times passing urine, pain, feeling unwell, bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, angioedema (symptoms such as wheezing, swelling of the face or tongue), kidney problems, impotence, increased sweating, discomfort or enlargement of the breasts in men, weight increase or decrease,
- Rare side effects (occur in less than 1 in 1000 users but in more than 1 in 10,000 users): confusion.
- Very rare side effects (occur in less than 1 in 10,000 users): cardiovascular disorders (irregular heartbeat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), swelling of eyelids, face or lips, swelling of the tongue and throat, which causes great difficulty in breathing, severe skin reactions including 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), erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), sensitivity to light, disorders of the blood, inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell, abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests, abdominal bloating (gastritis), disorder of the nerves which can cause weakness, tingling or numbness, increased muscle tension, vasculitis (inflammation of blood vessels), swelling of the gums, excess sugar in blood (hyperglycaemia).
- The following side effects have also been reported by patients taking ACERYCAL: hypoglycaemia (very low blood sugar level), disorders combining rigidity, tremor, and/or movement disorders.

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 HPRC 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 ACERYCAL

Keep out of the reach and sight of children.

Do not use ACERYCAL after the expiry date which is stated on the carton and bottle.- The expiry date refers to the last day of that month. Keep the bottle tightly closed in order to protect from moisture. Store in the original package.

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 ACERYCAL contains

- The active substances are perindopril arginine and Amlodipine. ACERYCAL 5mg/5mg: one tablet contains 5mg perindopril arginine and 5mg Amlodipine. ACERYCAL 10mg/5mg: one tablet contains 10mg perindopril arginine and 5mg Amlodipine.

ACERYCAL 5mg/10mg: one tablet contains 5mg perindopril arginine and 10mg Amlodipine.

ACERYCAL 10mg/10mg: one tablet contains 10mg perindopril arginine and 10mg Amlodipine.

- The other ingredients in the tablet are: lactose monohydrate, magnesium stearate, cellulose microcrystalline, colloidal anhydrous silica.

What ACERYCAL looks like and contents of the pack

ACERYCAL 5mg/5mg tablets are white, rod-shaped tablets engraved with 5/5 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 5mg/5mg' in its source country.

ACERYCAL 10mg/5mg tablets are white, triangular-shaped tablets engraved with 10/5 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 10mg/5mg' in its source country.

ACERYCAL 5mg/10mg tablets are white, square-shaped tablets engraved with 5/10 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 5mg/10mg' in its source country.

ACERYCAL 10mg/10mg tablets are white, round tablets engraved with 10/10 on one face and the company logo on the other face. This product is known as 'Co-Prestarium 10mg/10mg' in its source country.

The tablets are supplied in containers of 30 tablets.

Product procured from within the EU by the Parallel Product Authorisation

Holder:

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

Manufacturer

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

Repackaged by:

IMED Pharma Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

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

Belgium	COVERAM
Bulgaria	PRESTARUM-CO
Cyprus	COVERAM
Czech Republic	PRESTANCE
Denmark	COVERSICAL
Estonia	COVERAM
Finland	COVERAM
France	COVERAM
Hungary	ARMIXXAM
Iceland	COVERSICAL
Ireland	ACERYCAL
Italy	COVERLAM
Latvia	PRESTERAM
Lithuania	PRESTERAM
Luxembourg	COVERAM
Malta	COVERAM
Netherlands	COVERAM arg
Poland	Co-Prestarium
Portugal	COVERAM
Romania	PRESTANCE
Slovakia	PRESTANCE
Slovenia	PRESTANCE
Spain	COVERLAM
United Kingdom	ACERYCAL

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