

PACKAGE LEAFLET: INFORMATION FOR THE USER

ACERYCAL® 5mg/10mg tablets perindopril arginine / amlodipine

Your medicine is available using the above names but will be referred to as ACERYCAL throughout this leaflet.

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:

- What ACERYCAL is and what it is used for
- Before you take ACERYCAL
- How to take ACERYCAL
- Possible side effects
- How to store ACERYCAL
- 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 (angiotensin 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. 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 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.

Take special care with 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.

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.

Taking other medicines

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

You should avoid 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. 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, including 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 1,000 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 discolouration, back pain, muscle or joint pain, chest pain, disorder in passing urine, increased need to urinate at night, increased number of times of 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 1,000 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 heart beat, 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 movements disorders.

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.

5. HOW TO STORE ACERYCAL

- Keep out of the sight and reach 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.
- If your medicine appears to be discoloured, damaged or shows any other signs of deterioration, please return it to your pharmacist who will advise you further.
- 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. Each tablet contains 3.395mg perindopril equivalent to 5mg perindopril arginine and 13.870mg amlodipine besilate equivalent to 10mg amlodipine.
- The other ingredients in the tablet are: lactose monohydrate, magnesium stearate (E470B), cellulose microcrystalline (E460), colloidal anhydrous silica (E551).

What ACERYCAL looks like and contents of the pack

ACERYCAL 5mg/10mg tablets are white, square-shaped tablets engraved with 5/10 on one face and  on the other face.

ACERYCAL comes in packs of 30 tablets in a plastic container equipped with a flow reducer and a stopper containing a desiccant gel, in an outer carton.

Manufacturer

Your medicine is manufactured by:
Anpharm Przedsiębiorstwo Farmaceutyczne S.A.,
ul. Annopol 6B, 03-236 Warsaw, Poland.

Procured from within the EU by the PPA holder:
Imbat Ltd., Santry, Dublin 9.

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

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

PPA No: 1151/167/2

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
Greece 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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