

AMOPRIL TABLET

Amlodipine / Perindopril tert-butylamine (5mg/4mg, 5mg/8mg, 10mg/4mg, 10mg/8mg)

What is in this leaflet

1. What Amopril Tablet is used for
2. How Amopril Tablet works
3. Before you use Amopril Tablet
4. How to use Amopril Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Amopril Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Amopril Tablet is used for

Amopril Tablet 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 Amopril Tablet which contains both ingredients.

How Amopril Tablet works

Amopril Tablet is a combination of two active ingredients, perindopril and amlodipine. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines). Perindopril is an ACE (angiotensin converting enzyme) inhibitor. Together they work to widen the blood vessels, thus making it easier for your heart to pump blood into it.

Before you use Amopril Tablet

-When you must not use it

Do not take this medicine if you:

- allergic to perindopril tert-butylamine or any other ACE inhibitor, amlodipine or any other dihydropyridines, or any of the other ingredients of this medicine
- more than 3 months pregnant (it is also better to avoid Amopril Tablet in early pregnancy – see pregnancy section)
- 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)

- have cardiogenic shock (when the heart is unable to supply sufficient blood to the body), aortic stenosis (narrowing of the main blood vessels leading from the heart)
- have severe low blood pressure (severe hypotension)
- suffer from heart failure after an acute heart attack,
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

-Before you start to use it

Tell your doctor if you have or had any of the following conditions:

- hypertrophic cardiomyopathy (cardiac muscle disease) or renal artery stenosis (narrowing of the artery which supplies the kidney with blood)
- heart problems
- impaired liver function
- kidney problems or if you are receiving dialysis
- collagen vascular disease (disease of the connective tissue) such as systemic lupus erythematosus or scleroderma
- diabetes
- on a salt restricted diet or use salt substitutes which contain potassium (a well-balanced potassium blood level is essential)
- 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.
- taking any of the following

medicines, the risk of angioedema is increased:

- racecadotril (used to treat diarrhea),
- medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus),
- vildagliptin, a medicine used to treat diabetes

When you are taking Amopril Tablet, 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

-Taking other medicines

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

You should avoid Amopril Tablet with:

- lithium (used to treat mania or depression),
- estramustine (used in cancer therapy),
- potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).

Please tell your doctor or pharmacist if you are taking following medicines as special care may be required:

- other medicines for high blood pressure, including angiotensin II receptor blocker (ARB), aliskiren and diuretics (medicines which increase the amount of urine produced by the kidneys)
- non-steroidal anti-inflammatory

AMOPRIL TABLET

Amlodipine / Perindopril tert-butylamine (5mg/4mg, 5mg/8mg, 10mg/4mg, 10mg/8mg)

- drugs (e.g. ibuprofen) for pain relief or high dose acetylsalicylic acid
- 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 defense mechanism of the body) used for the treatment of auto-immune disorders of 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 used to treat muscle stiffness in diseases such as multiple sclerosis,
- rifampicin, erythromycin, clarithromycin (antibiotics)
- 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)

- simvastatin (cholesterol lowering medicine)
- medicines, which is most often used to treat diarrhea (racecadotril) or avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors).

Some medicines can increase the chance of getting side effects if you take them with Amopril Tablet:

- Tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ)
- Clarithromycin (for infections caused by bacteria).

How to use Amopril Tablet

-How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. This will normally be one tablet per day.

Amopril Tablet will usually be prescribed for patients already taking perindopril and amlodipine from separate tablets.

Children and adolescent

Amopril Tablet is not recommended for use in children and adolescents.

-When to use it

Swallow your tablet with a glass of water, preferably at the same time each day in the morning, before a meal.

-How long to use it

As the treatment with Amopril Tablet 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 medicine, ask your doctor or pharmacist.

-If you forget to use it

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

to take a dose of Amopril Tablet, take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

-If you use too much (overdose)

If you take too many tablets, contact your nearest accident and emergency department or tell your doctor immediately. The most likely symptoms of overdose are low blood pressure which can make you feel dizzy or faint. If this happens, lying down with legs raised can help.

While you are using it

-Things you must do

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Amopril Tablet 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.

Amlodipine **has been shown** to pass into breast milk in **small amounts**. If you are breastfeeding or about to start breast-feeding you must tell your doctor before taking Amopril Tablet.

-Things you must not do

Do not stop taking Amopril Tablet or lower the dosage without checking with your doctor.

Do not take any new medicines without consulting your doctor.

Do not give your medicine to anyone else, even if they have the same condition as you.

-Things to be careful of

Driving and using machines

Amopril Tablet does not affect alertness but you might experience dizziness or weakness due to low blood pressure which could affect your ability to drive or operate machinery. You are advised not to drive a car or operate machinery until you know how Amopril Tablet affects you.

AMOPRIL TABLET

Amlodipine / Perindopril tert-butylamine (5mg/4mg, 5mg/8mg, 10mg/4mg, 10mg/8mg)

Amopril Tablet with food and drink Grapefruit juice and grapefruit should not be consumed by people who are taking Amopril Tablet which can cause an unpredictable increase in the blood pressure lowering effect of Amopril Tablet.

Side effect

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Visit your doctor immediately if you experience any of the following side effects after taking this medicine:

- symptoms of allergic reaction such as swelling of the face, lips, mouth, tongue or throat, difficulty in breathing
- severe dizziness or fainting,
- unusual fast or irregular heartbeat.
- 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, toxic epidermal necrolysis) or other allergic reactions

Other side effects include:

Common side effects (occur in less than 1 in 10 users but in more than 1 in 100 users): headache, dizziness, vertigo, pins and needles, somnolence (sleepiness), vision disturbances, tinnitus (sensation of noises in the ears), palpitations (very fast heartbeat), flushing (hot or warm feeling in your face), 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), ankle swelling, muscle cramps, feeling of tiredness, oedema (swelling of your legs or ankles).

Uncommon side effects (occur in less than 1 in 100 users but in more than 1 in 1000 users): mood swings, sleep disturbances, trembling, syncope (temporary loss of consciousness), rhinitis (blocked up or runny nose), changed bowel habits, hair loss, red or discoloured patches on skin. Back, muscle or joint pain, chest pain. Increased need to urinate especially during the night, malaise (general feeling of being unwell), bronchospasm (tightening of the chest, wheezing and shortness of breath), dry mouth, weight increase or decrease, eosinophilia, hyperkalaemia, reversible on discontinuation, hyponatraemia, insomnia, pemphigoid, pollakiuria, renal failure, impotence, erectile dysfunction, pyrexia, fall. Allergic reactions, high potassium, low sodium, depression, loss of sensation in a part of body, pins and needles, visual disturbance, ringing in ears, hypotension, vomiting, pain in the upper abdomen, diarrhea, constipation, swelling of face, lips, mucous membrane, tongue, glottis and/or larynx. Small blood vessels burst, excessive sweat, itchy, red and rash skin, rare autoimmune disorder, painful, life-threatening skin condition, breast enlargement in man, swelling of lower legs or hands, abnormal physical weakness or lack of energy.

Rare side effects (occur in less than 1 in 1000 users): Syndrome of inappropriate antidiuretic hormone secretion (SIADH), confusion, serum bilirubin and liver enzymes elevation, psoriasis worsening, Acute renal failure, Anuria/Oliguria

Very rare side effects (occur in less than 1 in 10,000 users): confusion, cardiovascular disorders (irregular heartbeat, angina, heart attack and stroke), eosinophilic pneumonia (a rare type of pneumonia), erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), peripheral neuropathy (disease that produces loss of

sensations, pain, inability to control muscles), hypertonia (abnormal increase in muscle tension), vasculitis (inflammation of blood vessels of the skin), swelling of the gums, high blood sugar, cerebrovascular accident possibly secondary to excessive hypotension in high-risk patients. Blood and lymphatic disorders (a decrease in the number of white blood cells, extremely low number of granulocytes, low blood platelet count, red blood cells are destroyed faster, decrease in haemoglobin and haematocrit. Allergic reactions, inflammation and swelling of the mucous membrane of the nose, cough, pancreatitis, gastritis, inflammation of the liver, jaundice, feeling of rapidly progressing obstruction, swelling of face, lips, mucous membrane, tongue, glottis and/or larynx.

Not known (frequency cannot be estimated from available data): involuntary or uncontrollable movements. tremors. muscle contractions (extrapyramidal disorder), vasculitis (inflammation of blood vessels), increases in blood urea and serum creatinine, hyperkalaemia, numbness and pain in fingers or toes (Raynaud's phenomenon).

The following side effects have also been reported by patients taking Amopril Tablet: hypoglycaemia (very low blood sugar level).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF)/ Vaccines (AEFI).

Storage and Disposal of Amopril Tablet

-Storage

Keep out of the reach and sight of children.

Store below 30°C. Store in the original package in order to protect from light and moisture.

AMOPRIL TABLET

Amlodipine / Perindopril tert-butylamine (5mg/4mg, 5mg/8mg, 10mg/4mg, 10mg/8mg)

Do not use Amopril Tablet after the expiry date stated on the packaging.

-Disposal

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.

Product Description

What it looks like

Amopril Tablet 5mg/4mg:

White or almost white, round, 7 mm in diameter, biconvex tablets

Amopril Tablet 5mg/8mg:

White or almost white, round, 9 mm in diameter, biconvex tablets, debossed with "100" on one side and "Λ5" on the second side

Amopril Tablet 10mg/4mg:

White or almost white, round, 9 mm in diameter flat, tablets, debossed with "15" on one side

Amopril Tablet 10mg/8mg:

White or almost white, round, 9.5 mm in diameter, biconvex tablets, debossed with "5" on one side

Ingredients

Amopril Tablet 5mg/4mg:

Active ingredient(s): Amlodipine 5mg and Perindopril Tert-butylamine 4mg

Amopril Tablet 5mg/8mg:

Active ingredient(s): Amlodipine 5mg and Perindopril Tert-butylamine 8mg

Amopril Tablet 10mg/4mg:

Active ingredient(s): Amlodipine 10mg and Perindopril Tert-butylamine 4mg

Amopril Tablet 10mg/8mg:

Active ingredient(s): Amlodipine 10mg and Perindopril Tert-butylamine 8mg

Inactive ingredients:

Microcrystalline Cellulose (type 200XLM), Microcrystalline Cellulose (type 112), Sodium Starch Glycolate (type A), Silica Colloidal Anhydrous and Magnesium Stearate.

-MAL Number(s)

Amopril Tablet 5mg/4mg:

MALXXXXXXXXXX

Amopril Tablet 5mg/8mg:

MALXXXXXXXXXX

Amopril Tablet 10mg/4mg:

MALXXXXXXXXXX

Amopril Tablet 10mg/8mg:

MALXXXXXXXXXX

Manufacturer

Adamed Pharma S.A.
ul. Marszałka Józefa Piłsudskiego 5
95-200 Pabianice, Poland

Product Registration Holder

Pharmaniaga Marketing Sdn. Bhd.
(198401005734),
No. 7 Lorong Keluli 1B, Kawasan Perindustrian Bukit Raja Selatan, Seksyen 7, 40000 Shah Alam, Selangor Darul Ehsan, Malaysia

Date of Revision:

14/02/2022

Serial Number

NPRA (R1) 20/029