

**PACKAGE LEAFLET**

## Package leaflet: Information for the user

**.../ 5 mg/10 mg film-coated tablets**  
**.../ 10 mg/10 mg film-coated tablets**

Amlodipine/atorvastatin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What .../ is and what it is used for
2. What you need to know before you take .../
3. How to take .../
4. Possible side effects
5. How to store .../
6. Contents of the pack and other information

#### **1. What .../ is and what it is used for**

.../ contains two active substances, amlodipine and atorvastatin. Amlodipine belongs to the group of medicines called ‘calcium channel blockers’ and is used to treat high blood pressure (hypertension). Atorvastatin belongs to a group of medicines called ‘statins’ and is used to reduce the amount of fats (cholesterol and triglycerides) in the blood.

.../ is used for the prevention of cardiovascular (heart and blood vessels) events (for example angina pectoris, heart attack or stroke) in people with high blood pressure who have additional cardiovascular risk factors, such as tobacco smoking, being overweight, elevated blood cholesterol levels, a family history of heart disease or diabetes. If such factors are present in people with high blood pressure, there is an increased risk for developing cardiovascular events.

#### How .../ works

High blood pressure is a condition during which blood pressure stays abnormally high; it is one of the risk factors for cardiovascular events (for example angina pectoris, heart attack or stroke). Amlodipine works by relaxing blood vessels, so that blood passes through them more easily.

Cholesterol is a naturally occurring substance in the human body and is necessary for normal growth of the body. If there is too much cholesterol in your blood, fatty deposits can build up in the walls of your blood vessels causing them to narrow or eventually to become blocked. This is one of the most common causes of heart diseases.

Atorvastatin works by lowering high levels of ‘bad’ cholesterol (LDL-C) and raising the levels of ‘good’ cholesterol (HDL-C) in the blood. It works by blocking an enzyme in the liver that your body uses to make cholesterol. It also improves your body’s ability to remove the cholesterol from your blood stream.

#### **2. What you need to know before you take .../**

##### **Do not take .../ if you:**

- are allergic to amlodipine or another calcium channel blocker, atorvastatin, or any of the other

- ingredients of this medicine (listed in section 6).
- have or have ever had liver disease (see also below section ‘*Warnings and precautions*’).
  - have had abnormal liver test results.
  - have severe low blood pressure (hypotension).
  - have cardiogenic shock (a condition where your heart is unable to supply enough blood to your body).
  - have narrowing of the aortic heart valve (aortic stenosis).
  - suffer from heart failure after a heart attack.
  - are pregnant or if you are breast-feeding or not using appropriate contraceptive measures.
  - are taking any of the following medicines: ketoconazole, itraconazole (medicines used to treat fungal infections), telithromycin (an antibiotic drug).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking /.../ if you:

- have a history of liver disease.
- are over 70 years of age.
- have kidney problems.
- have an under-active thyroid gland (hypothyroidism).
- have had repeated or unexplained muscle aches or pains or if you have a personal or family history of muscle problems.
- have ever had a previous history of muscle problems when taking other cholesterol-lowering medicines (e.g. other ‘statins’ or ‘fibrates’).
- regularly drink large amounts of alcohol.
- if you have previously had a stroke with cerebral bleeding, or if you have small collections of fluid in the brain due to previous strokes.

If any of the above applies to you, your doctor may need to perform blood tests before and possibly during your treatment with /.../ to assess your risk of developing muscle related adverse effects.

### During treatment with /.../

If you observe unexplained muscle pain (myalgia), cramps, soreness or fatigue, especially if accompanied by malaise or fever, contact a doctor immediately, since treatment with /.../ might need to be discontinued. You should also contact your doctor if you start to experience difficulty in breathing, coughing and deterioration in your general health (fatigue, weight loss and fever).

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

### **Children and adolescents**

Do not give this medicine to children or adolescents because it is unlikely to be safe.

### **Other medicines and /.../**

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

There are some medicines that may change the effect of /.../, or their effect may be changed by /.../. This type of interaction could make one or both of the medicines less effective. Alternatively it could increase the risk or severity of side effects, including the important but rare muscle disorders known as ‘rhabdomyolysis’ and ‘myopathy’ (see section 4).

Tell your doctor if you are taking any of the following medicines:

- Some antibacterial agents such as rifampicin or fucidic acid or some macrolide antibiotics such as erythromycin, clarithromycin, telithromycin or some medicinal products used to treat fungal infections such as voriconazole, fluconazole, posiconazole, ketoconazole, itraconazole.
- Medicines used to control blood lipid levels: fibrates, such as gemfibrozil, nicotinic acid, colestipol and ezetimibe.
- Medicines used to control your heart rate such as amiodarone, diltiazem, or heart rhythm such as digoxin.
- Medicines used to treat and prevent seizures such as carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone, stiripentol.
- Medicines used to modify the way your immune system works, e.g. ciclosporin.
- Protease inhibitors and other medicines used to treat HIV, e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, nelfinavir, efavirenz, delavirdine.
- Warfarin (a blood thinning medicine).
- Ezetimibe (which reduces cholesterol)
- Stiripentol (an anticonvulsive for treating epilepsy)
- Cimetidine (used for heartburn and peptic ulcers),
- Phenazone (an analgesic)
- Antacids (used for digestive problems).
- Oral contraceptives (“the pill”).
- Boceprevir (used to treat liver disease such as hepatitis C)
- Medicines used to treat depression, such as nefazodone and imipramine.
- Medicines used to treat mental disorders such as antipsychotics.
- Medicines used to treat heart failure such as beta blockers (e.g. bisoprolol, carvedilol, metoprolol).
- Medicines used to treat high blood pressure (such as angiotensin receptor blockers, beta-blockers, calcium channel blockers, ACE- inhibitors, diuretics and nitrates).
- Alpha-1 blockers used to treat high blood pressure or some prostate conditions (e.g. prazosin, alfuzosin, doxazosin, tamsulosin, terazosin).
- Amifostine (used to treat cancer).
- Sildenafil (used to treat erectile dysfunction, impotence).
- Dantrolene and baclofen (muscle relaxants).
- Corticosteroids (medicines used to treat inflammatory conditions in your body).
- Over-the-counter herbal products containing St John’s wort (used to treat depression).

**/.../ with food , drink and alcohol**

/.../ may be taken at any time of day with or without food.

Grapefruit juice

Do not drink much grape fruit juice during treatment with /.../, since drinking large amounts (more than 1 to 2 glasses a day) of grapefruit juice can alter the effects of /.../.

Alcohol

Avoid drinking too much alcohol while taking /.../. See also ‘Warnings and precautions’ in this section.

**Pregnancy and breast-feeding**

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

Pregnancy

You must not use /.../ if you are pregnant, or if you are trying to become pregnant. Women of child bearing potential must use secure contraceptives during treatment with /.../.

Breast-feeding

You must not use /.../ if you are breast-feeding.

**Driving and using machines**

Do not drive or use machinery if you feel dizzy after taking this medicine..

### **3. How to take /.../**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### Adults

The usual starting dose is one tablet of /.../ 5 mg/10 mg, daily. If necessary, your doctor may increase your dose to one tablet of /.../ 10 mg/10 mg, daily.

Tablets should be swallowed whole with a little water. They may be taken at any time of day with or without food. However, it is recommended to take them at the same time every day.

Keep following your doctor's dietary advice, especially a diet restricted in fat, avoid smoking and take regular exercise.

If you feel that the effect of /.../ is too strong or too weak, talk to your doctor or pharmacist.

#### Use in children and adolescents

This medicinal product is not recommended in children and adolescents.

#### **If you take more /.../ than you should**

If you have taken more tablets of /.../ than you should (more than your usual dose), the most likely side effect is very low blood pressure (hypotension). Contact your doctor or go to the nearest hospital emergency department for advice. Take any remaining tablets and the carton or container with you so that the hospital staff can easily identify what medicine you took.

#### **If you forget to take /.../**

If you miss a dose of /.../, take the next dose at the normal time. Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking /.../**

Stopping your treatment with /.../ may cause your condition to get worse. Do not stop taking your medicine unless your doctor tells you to.

If you have any further questions on the use of this medicine, or if you wish to stop your treatment ask your doctor or pharmacist.

### **4. Possible side effects**

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

**If any of the following occurs, stop taking /.../ and contact a doctor or go to the nearest hospital straight away, as you may need urgent medical attention:**

- Swelling of the face, tongue or airways that could cause major breathing difficulties.
- If you have unexplained muscle weakness, muscle tenderness or pain in the muscles and at the same time you feel unwell or have a fever (in rare instances, this combination of effects turns out to be a serious, life-threatening illness called rhabdomyolysis).

#### **Other possible side effects:**

**Common** (may affect up to 1 in 10 people):

- Allergic reaction

- Increase in blood sugar levels (if you are diabetic you must continue to carefully monitor your blood sugar levels)
- Headache (especially at the start of treatment), dizziness, feeling of tiredness, drowsiness
- Redness of skin (flushing)
- Irregular heartbeat (palpitations)
- Inflammation of the nasal passage
- Throat pain, nosebleed
- Feeling sick (nausea), abdominal pain, upset stomach (indigestion) change in bowel habits (including diarrhoea, constipation and flatulence (wind))
- Muscle and joint pain, muscle cramps, muscle spasms, back pain, pain in the limbs
- Swelling of the arms, hands, legs, joints or feet (oedema)
- Changes seen in blood tests such as increase in the enzyme 'creatine phosphokinase' and certain liver enzymes.

**Uncommon** (may affect up to 1 in 100 people):

- Hepatitis (inflammation of the liver)
- Difficulty in sleeping
- Decrease in blood sugar levels (if you are diabetic, you must continue to carefully monitor your blood sugar levels)
- Fainting (syncope)
- Loss of appetite
- Weight gain or loss
- Mood changes, anxiety, depression, tremors, nightmares
- Memory loss, reduced sense of touch or pain, prickling or tingling of fingers or toes
- Vision problems (including double vision), blurred vision, buzzing or ringing in your ears (tinnitus)
- Decreased blood pressure
- Shortness of breath (difficulty in breathing)
- Dry mouth, taste changes, vomiting, stuffy nose (rhinitis), belching
- Skin rash or itching, itchy skin rash (urticaria) hair loss, bruising or tiny spots on the skin, skin discoloration, increased sweating
- Neck pain, muscle weakness
- Chest pain
- Urinary disorders (excessive urination at night and increased frequency of urination)
- Impotence, swelling of the breast tissue in men
- Sensation of discomfort, feeling weak, pain, general feeling of being unwell (malaise), fever
- White blood cells in the urine.
- Pancreatitis (inflammation of the pancreas that causes stomach pain)

**Rare** (may affect up to 1 in 1,000 people):

- Visual disturbance
- Unexpected bleeding or bruising
- Liver disorders (yellow colouration of the skin and whites of the eyes)
- Serious muscular inflammation, pain or very intense muscle cramps that can rarely lead to rhabdomyolysis (destruction of muscle cells) and abnormal muscle breakdown. The abnormal muscle breakdown does not always go away, even after you have stopped taking /.../ and it can be life-threatening and lead to kidney problems.
- Serious allergic skin reactions, reddening of the skin, rash with blisters, peeling skin that can quickly spread to the rest of the body and may onset with flu-like symptoms, accompanied by high fever
- Inflammation of the deep layers of the skin, including inflammation of the lips, eyelids and tongue.
- Reduced number of platelets in your blood
- Feeling confused
- Problems in the nerves of the arms or legs with symptoms such as decreased sensitivity and weakness ('peripheral neuropathy')
- Chest pain (angina)

- Blockage of bile ducts (cholestasis) with symptoms such as yellowing of eyes and skin and dark urine
- Swelling in the skin or mucous membranes
- Inflammation or swelling of the skeletal muscles (myositis), inflammation of the tendons or tendon injury.

**Very rare** (may affect up to 1 in 10,000 people):

- Allergic reaction: the symptoms could include sudden wheezing, chest tightness or pain, swelling of the eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse
- Gynaecomastia (increase in breast size in men and women)
- Decrease in the number of white blood cells
- Stiffness or muscle tension
- Abnormal heart rhythm (slow or fast), heart attack, inflammation of the small blood vessels
- Inflammation of the gums (gingival hyperplasia)
- Inflammation of the lining of the stomach (gastritis)
- Cough
- Impaired hearing
- Liver failure
- Photosensitivity (sensitivity of the skin to sunlight).

**Not known** (frequency cannot be estimated from the available data):

- Sexual dysfunction
- Depression
- Inflammation of the lungs called ‘interstitial lung disease’ causing breathing difficulties, persistent cough and fever.
- Condition called ‘extrapyramidal syndrome’ with symptoms like involuntary movements, shaking, muscle rigidity and spasms, usually in the face and neck
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.
- Muscle weakness that is constant.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via [the national reporting system listed in Appendix V\\*](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store /.../**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after ‘EXP’. The expiry date refers to the last day of that month.

Store below 25°C

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What /.../ contains**

- The active substances are amlodipine and atorvastatin.  
Each film-coated tablet contains 5 mg amlodipine (as besilate) and 10 mg atorvastatin (as

calcium). Each film-coated tablet contains 10 mg amlodipine (as besilate) and 10 mg atorvastatin (as calcium).

- The other ingredients are:

*Tablet core:* Calcium carbonate, microcrystalline cellulose, pregelatinised maize starch, croscarmellose sodium, hydroxypropylcellulose, polysorbate 80, colloidal anhydrous silica, magnesium stearate.

*Film-coating:* <[ /.../ 5 mg/10 mg:]> Opadry II white 85F18422 containing polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol, talc. <[ /.../ 10 mg/10 mg:]> Opadry II blue 85F205038 containing polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol, talc, indigo carmine aluminium lake (E132).

### What /.../ looks like and contents of the pack

<[ /.../ 5 mg/10 mg:]> White film-coated tablets, oval shaped, biconvex, 4.2 mm x 8.2 mm in size, with the marking AA debossed on one side.

<[ /.../ 10 mg/10 mg:]> Blue film-coated tablets, oval shaped, biconvex, 4.2 mm x 8.2 mm in size, with the marking AA1 debossed on one side.

*Pack sizes:*

Blister packs: 28, 30, 90 and 100 film-coated tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

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

**PT:** Amlodipina + Atorvastatina ratiopharm

**BG:** Аванор плюс 5 mg/10 mg филмирани таблетки  
Аванор плюс 10 mg/10 mg филмирани таблетки

**CZ:** Amlodipin/Atorvastatin Teva 5mg/10mg  
Amlodipin/Atorvastatin Teva 10mg/10mg

**PL:** Atorvox Plus

**RO:** Amlodipină/Atorvastatină Teva 5mg/10mg comprimate filmate  
Amlodipină/Atorvastatină Teva 10mg/10mg comprimate filmate

**SK:** AMLOAT 5mg/10mg  
AMLOAT 10 mg/10mg

This leaflet was last revised in <{MM/YYYY}> <{month YYYY}>.

<[To be completed nationally]>