

Package leaflet: Information for the patient

Euvalcor 10 mg/5 mg hard capsules
Euvalcor 20 mg/5 mg hard capsules
Euvalcor 40 mg/5 mg hard capsules
Euvalcor 10 mg/10 mg hard capsules
Euvalcor 20 mg/10 mg hard capsules
Euvalcor 40 mg/10 mg hard capsules

atorvastatin / perindopril arginine

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor 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 Euvalcor is and what it is used for
2. What you need to know before you take Euvalcor
3. How to take Euvalcor
4. Possible side effects
5. How to store Euvalcor
6. Contents of the pack and other information

1. What Euvalcor is and what it is used for

Pharmacotherapeutic class: Serum lipid reducing agents, in combination. HMG-CoA reductase inhibitors, other combinations, ATC Code: C10BX

Euvalcor contains two active ingredients, atorvastatin and perindopril arginine in one capsule.

Atorvastatin belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines. Atorvastatin is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed. If you are at an increased risk of heart disease, atorvastatin can also be used to reduce such risk even if your cholesterol levels are normal.

Perindopril arginine is an angiotensin converting enzyme (ACE) inhibitor. In patients with high blood pressure, it works by widening the blood vessels, which makes it easier for your heart to pump blood through them.

Euvalcor is intended for adult patients already on treatment with atorvastatin and perindopril arginine as single tablets as part of cardiovascular risk management. Instead of taking atorvastatin and perindopril arginine as single tablets you will receive one capsule of Euvalcor which contains the two active ingredients in the same strength.

You should maintain a standard cholesterol lowering diet during treatment.

2. What you need to know before you take Euvalcor

Do not take Euvalcor :

- if you are allergic to atorvastatin or to any similar medicines used to lower blood lipids, to perindopril or any other ACE inhibitor, or to any of the other ingredients of this medicine (listed in section 6),
- if you have a disease which affects the liver,
- if you have any unexplained abnormal blood tests for liver function,
- if you have experienced symptoms such as wheezing, swelling of the face, tongue or throat, intense itching or severe skin rashes with previous ACE inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema),
- if you have diabetes or impaired kidney function and you are taking a blood pressure lowering medicine containing aliskiren,
- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Eivalcor may not be suitable for you.
- if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).
- if you are being treated with sacubitril/valsartan, a medicine for heart failure (see “Warning and Precaution” and “Other medicines and Eivalcor”).
- if you are pregnant or trying to become pregnant, or if you are a woman able to have children and not using reliable contraception,
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Eivalcor if you:

- have a liver problem or a history of liver disease,
- regularly drink a large amount of alcohol,
- are taking or have taken in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Eivalcor can lead to serious muscle problems (rhabdomyolysis),
- have had repeated or unexplained muscle aches or pains, have, or if a close family member has a muscle problem which runs in the family,
- have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other ‘-statin’ or ‘-fibrate’ medicines),
- have an under-active thyroid gland (hypothyroidism),
- have severe respiratory failure,
- have diabetes (high blood glucose),
- have heart failure or any other heart problem,
- have recently suffered from diarrhoea or vomiting, or are dehydrated,
- have aortic stenosis (narrowing of the main blood vessel leading from the heart) or hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
- have kidney problems, recently underwent a kidney transplantation or if you are receiving dialysis,
- have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism),
- are elderly (over 70),
- are experiencing a severe allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing (angioedema). This may occur at any time during treatment. If you develop such symptoms, you should stop taking Eivalcor and see a doctor immediately.
- suffer from a collagen vascular disease (deposits of collagen in your blood vessels), such as systemic lupus erythematosus or scleroderma,
- are of black origin since you may have a higher risk of angioedema and this medicine may be less effective in lowering your blood pressure than in non-black patients,
- are taking any of the following medicines, the risk of angioedema is increased:
 - racecadotril (used to treat diarrhea)
 - sirolimus, everolimus, temsirolimus and other drugs belonging to the class of so-called mTor inhibitors (used to avoid rejection of transplanted organs),

- sacubitril (available as fixed dose combination with valsartan) used to treat long-term heart failure,
- are to undergo LDL apheresis (which is 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,
- are to undergo anaesthesia and/or major surgery
- are on a salt restricted diet or use salt substitutes which contain potassium,
- have been told by your doctor that you have an intolerance to some sugars,
- 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 Eivalcor”.

If any of these apply to you, your doctor may need to carry out a blood test before and possibly during your treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g rhabdomyolysis is known to increase when certain medicines are taken at the same time (see section 2 “Other medicines and Eivalcor”).

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.

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 fat in your blood, are overweight and have high blood pressure.

Children and adolescents

The use of Eivalcor in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Eivalcor

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 Eivalcor or their effect may be changed by Eivalcor. 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 muscle wasting condition known as rhabdomyolysis described in Section 4.

Eivalcor must not be used with:

- aliskiren (used for high blood pressure) in diabetic or renal impaired patients,
- sacubitril/valsartan (used to treat long-term heart failure). See sections “Do not take Eivalcor” and “Warnings and precautions”.

You should avoid Eivalcor with:

- 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, tacrolimus),
- clarithromycin, telithromycin (antibiotics),
- medicines used in the treatment of HIV or liver disease such as Hepatitis C, e.g. delavirdine, ritonavir, lopinavir, atazanavir, indinavir, darunavir, telaprevir, boceprevir, tipranavir, elbasvir, or grazoprevir,
- stiripentol (an anti-convulsant for epilepsy),
- ketoconazole, itraconazole, voriconazole, posaconazole (anti-fungal medicines),
- other medicines for high blood pressure, including aliskiren in patients other than diabetic or renal impaired, angiotensin II receptor blockers (e.g. valsartan) see also information under the headings “Do not take Eivalcor” and “Warnings and precautions”, or diuretics (medicines which increase the amount of urine produced by the kidneys),
- estramustine (used in cancer therapy),
- lithium for mania or depression,

- medicines, which are 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). See section “Warnings and precautions”.
- potassium-sparing drugs (e.g. triamterene, amiloride, eplerenone, spironolactone), potassium supplements or potassium-containing salt substitutes, other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole).

Treatment with Eivalcor 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:

- fluconazole (anti-fungal medicines),
- rifampicin, erythromycin, fusidic acid, trimethoprim (antibiotics),
- some calcium channel blockers used for angina or high blood pressure, e.g. diltiazem, verapamil,
- efavirenz (medicine used in the treatment of HIV),
- medicine obtained without a prescription: *hypericum perforatum* or St John’s Wort (herbal treatment used for depression),
- medicines to regulate your heart rhythm e.g. digoxin, amiodarone, procainamide,
- other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol, ezetimibe,
- medicines which reduce blood clotting (anticoagulants, such as warfarin, heparin),
- baclofen (used to treat muscle stiffness in diseases such as multiple sclerosis),
- non-potassium-sparing diuretics (medicines which increase the amount of urine produced by the kidneys),
- medicines to treat diabetes (such as insulin or metformin),
- non-steroidal anti-inflammatory drugs (e.g. ibuprofen) for pain relief or treatment of inflammation (e.g. in case of rheumatoid arthritis) or high dose aspirin.

If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using Eivalcor. Your doctor will tell you when it is safe to restart Eivalcor. Taking Eivalcor with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

The use of Eivalcor should be taken into consideration with:

- colchicine (used in the treatment of gout, a disease with painful, swollen joints caused by uric acid crystals),
- other medicines to regulate lipid levels, e.g. colestipol,
- oral contraceptives,
- medicines used for the treatment of low blood pressure, shock (e.g. ephedrine, noradrenaline or adrenaline),
- some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine,
- medicines to treat mental disorders such as depression, anxiety, schizophrenia etc (e.g. tricyclic antidepressants, antipsychotics),
- gold salts, especially by intravenous administration (used to treat symptoms of rheumatoid arthritis),
- vasodilators including nitrates (products that make the blood vessels become wider),
- cimetidine (used for heartburn and peptic ulcers),
- phenazone (a painkiller),
- antacids (indigestion products containing aluminium or magnesium),
- allopurinol (for the treatment of gout).

Eivalcor with food, drink and alcohol

It is preferable to take Eivalcor in the morning before breakfast.

Grapefruit and grapefruit juice

If you are taking Eivalcor, you should not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice will lead to an increased effect of the active ingredient atorvastatin.

Alcohol

Avoid drinking too much alcohol while taking this medicine. See Section 2 “Warnings and precautions” for details.

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

Do not take Euvalcor if you are pregnant, if you are trying to become pregnant or if able to become pregnant unless you use reliable contraceptive measures (see “Do not take Euvalcor”).

This medicine must not be used during pregnancy.

Breast-feeding

You must not take Euvalcor if you are breast-feeding. Tell your doctor immediately if you are breast-feeding or about to start breast-feeding.

Driving and using machines

Euvalcor may cause dizziness or weakness. If you are affected in this way, your ability to drive or to operate machinery may be impaired.

Euvalcor contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Euvalcor contains sodium

Euvalcor contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

3. How to take Euvalcor

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

The recommended dose is one capsule per day. Swallow your capsule whole with a glass of water preferably at the same time each day, in the morning and before a meal. Do not chew or crush the capsules.

Use in children and adolescents

Use in children and adolescents younger than 18 years is not recommended.

If you take more Euvalcor than you should

If you take more capsules than prescribed, contact your nearest accident and emergency department or tell your doctor immediately. Taking too many capsules may cause your blood pressure to become low which can make you feel dizzy, lightheaded, faint or weak. If this happens, lying down with the legs raised can help. Taking too many capsules may also cause dizziness, headache, ringing in ears, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, passing less urine than is normal, agitation, seizures, hallucinations, low blood sugar, coma, shock and respiratory arrest.

If you forget to take Euvalcor

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

As the treatment with Euvalcor is usually life-long, you should discuss with your doctor before stopping this medicinal product.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking the medicinal product and see a doctor immediately, if you experience any of the following side effects that can be serious:

- swelling of eyelids, the face, lips, mouth, tongue or throat, difficulty in breathing (angioedema) (See section 2 “Warnings and precautions”),
- severe dizziness or fainting due to low blood pressure,
- 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,
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (rhabdomyolysis) which can be life-threatening and lead to kidney problems,
- weakness of arms or legs, or problems speaking which could be a sign of a possible stroke,
- unusual fast or irregular heartbeat, chest pain (angina) or heart attack,
- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm),
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell,
- if you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver failure,
- yellowing of the skin or eyes (jaundice) which could be a sign of inflammation of the liver (hepatitis)
- skin rash which often starts with red itchy patches on your face, arms or legs (erythema multiforme),

Tell your doctor if you notice any of the following side effects:

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

- inflammation of the nasal passages,
- increases in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in blood creatine kinase,
- vertigo, dizziness,
- headache,
- sensation of pins and needles in the skin,
- vision disturbances,
- tinnitus (sensation of noises or ringing in the ears),
- pain in the throat,
- nose bleed,
- cough, shortness of breath (dyspnoea),
- joint pain, pain in the extremities, joint swelling, muscle spasms, muscle pain, and back pain,
- feeling of weakness,
- blood test results that show your liver function can become abnormal,
- gastro-intestinal disorders: feeling sick (nausea), being sick (vomiting), constipation, wind, indigestion, diarrhoea, upper and lower abdominal pain, taste disturbances.

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

- excess of eosinophils (a type of white blood cells),
- anorexia (loss of appetite),
- insomnia,
- mood swings,
- sleep disturbances,
- having nightmares,

- somnolence,
- fainting,
- reductions of sensation to pain or touch,
- loss of memory,
- blurred vision,
- tachycardia (fast heart beat),
- palpitations (awareness of your heart beat),
- vasculitis (inflammation of blood vessels),
- dry mouth,
- belching,
- increased sweating,
- hair loss,
- formation of blister clusters over the skin,
- photosensitivity reaction (increased sensitivity of the skin to sun),
- neck pain,
- muscle fatigue,
- kidney problems,
- inability to obtain an erection, impotence,
- fatigue,
- chest pain,
- malaise,
- localised swelling (oedema peripheral),
- raised temperature (fever),
- weight gain,
- urine tests that are positive for white blood cells,
- fall,
- change in laboratory parameters: high blood level of potassium reversible on discontinuation, low level of sodium, very low blood sugar level (if you have diabetes you should continue careful monitoring of your blood sugar levels), increased blood urea, and increased blood creatinine.

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

- low blood platelet count which may result in unusual bruising or easy bleeding,
- disorder of the nerves which can cause weakness, tingling or numbness,
- cholestasis (yellowing of the skin and whites of the eyes),
- psoriasis worsening,
- muscle inflammation,
- tendon injury,
- changes in laboratory parameters: increased liver enzymes, increased serum bilirubin.

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

- sneezing/running nose caused by inflammation of the lining of the nose (rhinitis),
- changes in blood values such as a lower number of white and red blood cells, lower haemoglobin, illness resulting from the destruction of red blood cells,
- confusion,
- hearing loss,
- eosinophilic pneumonia (a rare type of pneumonia),
- acute kidney failure,
- discomfort or enlargement of the breasts in men.

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

- muscle weakness that is constant.

Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion can occur with ACE inhibitors. If you have these symptoms contact your doctor as soon as possible.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Euvalcor

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 carton and capsule container after EXP. The expiry date refers to the last day of that month.

Store in the original container in order to protect from moisture.
Store below 30°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 Euvalcor contains

- The active substances are atorvastatin and perindopril arginine.

Each hard capsule of Euvalcor 10 mg/5 mg contains 10.82 mg atorvastatin calcium trihydrate equivalent to atorvastatin 10 mg, 5 mg perindopril arginine equivalent to 3.395 mg perindopril

Each hard capsule of Euvalcor 20 mg/5 mg contains 21.64 mg atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin, 5 mg perindopril arginine equivalent to 3.395 mg perindopril

Each hard capsule of Euvalcor 40 mg/5 mg contains 43.28 mg atorvastatin calcium trihydrate equivalent to 40 mg atorvastatin, 5 mg perindopril arginine equivalent to 3.395 mg perindopril

Each hard capsule of Euvalcor 10 mg/10 mg contains 10.82 mg atorvastatin calcium trihydrate equivalent to 10 mg atorvastatin, 10 mg perindopril arginine equivalent to 6.79 mg perindopril

Each hard capsule of Euvalcor 20 mg/10 mg contains 21.64 mg atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin, 10 mg perindopril arginine equivalent to 6.79 mg perindopril

Each hard capsule of Euvalcor 40 mg/10 mg contains 43.28 mg atorvastatin calcium trihydrate equivalent to 40 mg atorvastatin, 10 mg perindopril arginine equivalent to 6.79 mg perindopril

- The other ingredients are:
 - **Pellets of atorvastatin:** calcium carbonate (E170), hydroxypropyl cellulose (E463), polysorbate 80 (E433), croscarmellose sodium (E468), sugar spheres (sucrose and maize starch).
 - **Pellets of perindopril:** hydroxypropyl cellulose (E463), sugar spheres (sucrose and maize starch).
 - **Talc**
 - **Capsule shell:**
 - **Euvalcor 10 mg/5 mg, 20 mg/5 mg and 40 mg/5 mg:** titanium dioxide (E171), brilliant blue FCF – FD&C Blue 1 (E133), gelatin,
 - **Euvalcor 10 mg/10 mg, 20 mg/10 mg and 40 mg/10 mg:** titanium dioxide (E171), brilliant blue FCF – FD&C Blue 1 (E133), yellow iron oxide (E172), gelatin,
 - **Printing ink :** shellac (E904), propylene glycol (E1520), strong ammonia solution (E527), black iron oxide (E172), potassium hydroxide (E525).

What Euvalcor looks like and contents of the pack

Euvalcor are hard gelatin size 2 capsules containing spherical white to slightly white spherical pellets.

Euvalcor 10 mg/5 mg hard capsules have a light blue body with a black imprint “10 5” and a light blue cap with a black imprint “”.

Euvalcor 20 mg/5 mg hard capsules have a light blue body with black imprint “20 5” and a blue cap with a black imprint “”.

Euvalcor 40 mg/5 mg hard capsules have a blue body with black imprint “40 5” and a blue cap with a black imprint “”.

Euvalcor 10 mg/10 mg hard capsules have a light green body with a black imprint “10 10” and a light green cap with a black imprint “”.

Euvalcor 20 mg/10 mg hard capsules have a light green body with a black imprint “20 10” and a green cap with a black imprint “”.

Euvalcor 40 mg/10 mg hard capsules have a green body with a black imprint “40 10” and a green cap with a black imprint “”.

The hard capsules are available in containers of 10 (available for 10 mg/5 mg strength only), 30 and 100. A presentation containing 90 capsules (3 containers of 30 capsules) is also available.

10, 30 and 100 hard capsules containers are closed with a stopper.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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