

## **Package leaflet: Information for the user**

**Rozemib 5 mg/10 mg, filmomhulde tabletten**  
**Rozemib 10 mg/10 mg, filmomhulde tabletten**  
**Rozemib 20 mg/10 mg, filmomhulde tabletten**  
**Rozemib 40 mg/10 mg, filmomhulde tabletten**

### **Rosuvastatin & Ezetimibe**

**Read all of this leaflet carefully before you start using 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 [Product Name] is and what it is used for
2. What you need to know before you use [Product Name]
3. How to use [Product Name]
4. Possible side effects
5. How to store [Product Name]
6. Contents of the pack and other information

#### **1. What [Product Name] is and what it is used for**

{Product Name} contains two different active substances in one film coated tablet. One of the active substances is rosuvastatin calcium, belonging to the group of so called statins, the other active substance is ezetimibe.

{Product Name} is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol) and fatty substances called triglycerides in your blood. In addition, it also raises levels of “good” cholesterol (HDL cholesterol). This medicine works to reduce your cholesterol in two ways: it reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself.

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. By lowering your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

{Product Name} is used in patients whose cholesterol levels cannot be controlled by a cholesterol lowering diet alone. You should stay on your cholesterol lowering diet while taking this medicine.

Your doctor may prescribe {Product Name} if you are already taking both rosuvastatin and ezetimibe at the same dose level.

{Product Name} is used if you have:

- a raised cholesterol level in your blood (primary hypercholesterolemia)

{Product Name} does not help you lose weight.

## **2. What you need to know before you use [Product Name]**

### **Do not use [Product Name]:**

- are allergic to rosuvastatin, ezetimibe or any of the other ingredients of this medicine (listed in section 6).
  - have liver disease.
  - have severe kidney impairment.
  - have repeated, unexplained muscle aches or pains (myopathy).
  - take a drug called ciclosporin (used for example, after organ transplants).
  - are pregnant or breast-feeding. If you become pregnant while taking {Product Name} stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking {Product Name} by using suitable contraceptive measures
- In addition, do not take rosuvastatin 40 mg (the highest dose):
- If you have moderate kidney problems (if in doubt, please ask your doctor).
  - have thyroid gland that is not working properly (hypothyroidism)
  - regularly drink large amounts of alcohol.
  - are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
  - take other medicines called fibrates to lower your cholesterol (see section “Other medicines and {Product Name}”).

If any of the above applies to you (or you are in doubt), please contact your doctor.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking {Product Name} if you:

- have problems with your kidneys.
  - have problems with your liver.
  - have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever. Also tell your doctor or pharmacist if you have a muscle weakness that is constant.
  - are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian). Your doctor needs to choose the right dose of {Product Name} to suit you.
  - take medicines used to fight infections, including HIV or hepatitis C infection e.g. lopinavir/ritonavir and/or atazanavir or simeprevir, please see “Other medicines and {Product Name}”.
  - have severe respiratory failure.
  - take other medicines called fibrates to lower your cholesterol. Please see “Other medicines and {Product Name}”.
  - regularly drink large amounts of alcohol.
  - have thyroid gland that is not working properly (hypothyroidism).
  - are over 70 (as your doctor needs to choose the right dose of {Product Name} to suit you).
- 
- 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 {Product Name} can lead to serious muscle problems (rhabdomyolysis).

If any of the above applies to you (or if you are not sure): check with your doctor or pharmacist before you actually start taking any dose of {Product Name}.

In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will regularly out this blood test (liver function test) during treatment with {Product Name}. It is important to go to the doctor for the prescribed laboratory checks.

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.

### **Children and adolescents**

The use of {Product Name} is not recommended in children and adolescents under the age of 18 years.

### **Other medicines and [Product Name]**

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

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

- Ciclosporin (used for example, after organ transplants to prevent rejection of the transplanted organ. The effect of rosuvastatin is increased with concomitant use). **Do not take {Product Name} while taking ciclosporin.**
- Blood thinners e.g. warfarin, acenocoumarol or fluindione (their blood thinning effect and the risk of bleeding may be increased while taken concomitantly with {Product Name}), or clopidogrel
- Other medicines to lower your cholesterol called fibrates, which correct also blood triglyceride levels (e.g. gemfibrozil and other fibrates). During concomitant use, the effect of rosuvastatin is increased.
- Colestyramine (a medicine for lowering cholesterol), because it affects the way ezetimibe works
- Antiviral medications such as ritonavir with lopinavir and/or atazanavir or simeprevir (used to treat infections, including HIV or hepatitis C infection). See section Warnings and precautions.
- Indigestion remedies containing aluminium and magnesium (used to neutralise acid in your stomach; they decrease the plasma level of rosuvastatin.) This effect may be mitigated with taking this type of medicine 2 hours after rosuvastatin.
- Erythromycin (an antibiotic). The effect of rosuvastatin is decreased with their concomitant use.
- Fusidic acid. If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart {Product Name}. Taking {Product Name} with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- An oral contraceptive (the pill). The levels of sexual hormones absorbed from the pill are increased.
- Hormone replacement therapy (increased hormone levels in the blood).
- Regorafenib (used to treat cancer)
- Simeprevir (used to treat chronic hepatitis C infection)

If you go into hospital or receive treatment for another condition, tell the medical staff that you are taking {Product Name}.

### **{Product Name} with alcohol**

Do not take {Product Name} 40 mg/10 mg (the highest dose), if you regularly drink large amounts of alcohol.

### **Pregnancy and breast-feeding**

Do not take {Product Name} if you are pregnant, are trying to get pregnant or think you may be pregnant. If you get pregnant while taking {Product Name}, stop taking it immediately and tell your doctor. Women should use contraceptive measures during the treatment with {Product Name}.

Do not take {Product Name}, if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

### **Driving and using machines**

{Product Name} are not expected to interfere with your ability to drive or to use machinery.

However, it should be taken into account that some people get dizzy after taking {Product Name}. If you get dizzy, talk to your doctor before driving or using machines.

### **{Product Name} contains lactose**

{Product Name} tablets contain a sugar called lactose. 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 use [Product Name]**

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

You should keep on being on low-cholesterol diet and doing exercises while taking {Product Name}. The recommended daily dose for adults is one tablet of the given strength.

### **Take {Product Name} once daily.**

You can take it at any time of the day, with or without food. Swallow each tablet whole with a drink of water.

Take your medicine at the same time every day.

{Product Name} is not suitable to start a treatment. Treatment initiation or dose adjustment if necessary should only be done by giving the active substances separately and after setting the appropriate doses the switch to {Product Name} of the appropriate strength is possible.

The maximum daily dose of rosuvastatin is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

### **Regular cholesterol checks**

It is important to go back to your doctor for regular cholesterol checks to make sure your cholesterol has reached and is staying at the correct level.

### **If you use more [Product Name] than you should**

Contact your doctor or the emergency department of the nearest hospital because you might need medical help.

### **If you forget to use [Product Name]**

Don't worry, skip the missed dose and take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

### **If you stop using [Product Name]**

Talk to your doctor if you want to stop taking {Product Name}. Your cholesterol levels might increase again if you stop taking {Product Name}.

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. It is important that you are aware of what these side effects may be.

Stop taking {Product Name} and seek medical help immediately if you experience any of the following allergic reactions:

- swelling of the face, lips, tongue and/or throat, which may cause difficulty in breathing and swallowing.
- lupus-like disease syndrome (including rash, joint disorders and effects on blood cells)
- muscle rupture

Contact your doctor immediately if you have any unusual muscle aches or pains which go on for longer than you might expect. Rarely this can develop into potentially life threatening muscle damage known as rhabdomyolysis, which leads to malaise, fever and kidney impairment.

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

Ulcers or blistering of the skin, mouth, eyes and genitals. These could be signs of Steven Johnson syndrome (a life-threatening allergic reaction affecting the skin and mucous membranes).

The following terms are used to describe how often side effects have been reported:

- Very common (may affect more than 1 of 10 patients)
- Common (may affect up to 1 of 10 patients)
- Uncommon (may affect up to 1 of 100 patients)
- Rare (may affect up to 1 of 1,000 patients)
- Very rare (may affect up to 1 of 10,000 patients, including isolated reports).

### **Common side effects**

- Headache
- Constipation
- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness
- 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.
- stomach ache;
- diarrhoea;

- flatulence (excess gas in the intestinal tract);
- feeling tired.
- elevations in some laboratory blood tests of liver function (transaminases);

#### Uncommon side effects

- Rash, itching, hives
- An increase in the amount of protein in the urine may occur – this usually returns to normal on its own without having to stop taking rosuvastatin
- elevations in some laboratory blood tests of muscle (CK) function;
- cough;
- indigestion;
- heartburn;
- joint pain;
- muscle spasms;
- neck pain;
- decreased appetite;
- pain;
- chest pain;
- hot flush;
- high blood pressure.
- tingling sensation;
- dry mouth;
- inflammation of the stomach,
- back pain;
- muscle weakness,
- pain in arms and legs;
- swelling, especially in the hands and feet.

#### Rare side effects:

Inflammation of the pancreas, which causes a severe stomach pain which can extend to the back, reduction in blood platelets

#### Very rare side effects:

jaundice (yellowing of the skin and eyes), inflammation of the liver (hepatitis), traces of blood in your urine, damage to the nerves of your legs and arms (such as numbness), memory loss, breast enlargement in men (gynecomastia)

#### Not known:

shortness of breath, oedema (swelling), sleep disturbances, including insomnia and nightmares, sexual difficulties, depression, breathing problems including persistent cough and/or shortness of breath or fever, tendon injury, muscle weakness that is constant, gallstones or inflammation of the gallbladder (which may cause stomach ache, nausea, vomiting)

#### 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 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 [Product Name]**

Store in the original package in order to protect from moisture and light. This medicinal product does not require any special temperature storage conditions.

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 bottle after EXP. The expiry date refers to the last day of that month.

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 [Product Name] contains**

The active substances are rosuvastatin (as rosuvastatin calcium) and ezetimibe.

<Product name> 5 mg/10 mg:

Each tablet contains 5.20 mg rosuvastatin calcium (equivalent to 5 mg rosuvastatin) and 10 mg of ezetimibe.

<Product name> 10 mg/10 mg:

Each tablet contains 10.40 mg rosuvastatin calcium (equivalent to 10 mg rosuvastatin) and 10 mg of ezetimibe.

<Product name> 20 mg/10 mg:

Each tablet contains 20.80 mg rosuvastatin calcium (equivalent to 20 mg rosuvastatin) and 10 mg of ezetimibe.

<Product name> 40 mg/10 mg:

Each tablet contains 41.60 mg rosuvastatin calcium (equivalent to 40 mg rosuvastatin) and 10 mg of ezetimibe.

### **The other ingredients are**

Tablet core (same for all strengths): Cellulose Micryostalline (E460), Silica, colloidal anhydrous (E551), Magnesium stearate (E572), Povidone K30 (E1201), Croscarmellose Sodium (E468), Sodium laurilsulfate (E487), Lactose Monohydrate, Hypromellose 2910 (E464),

Coating:

Opadry Yellow (5mg/10mg): Hypromellose 2910 (E464), Titanium Dioxide (E171), Macrogol 4000 (E1521), Iron Oxide Yellow (E172), Talc (E553b), Iron Oxide Red (E171),

Opadry Beige (10mg/10mg): Hypromellose 2910 (E464), Titanium Dioxide (E171), Macrogol 4000 (E1521), Iron Oxide Yellow (E172), Talc (E553b),

Vivacoat Yellow (20mg/10mg): Hypromellose 2910 (E464), Titanium Dioxide (E171), Macrogol 4000 (E1521), Iron Oxide yellow (E172), Talc (E553b),

Opadry white (40mg/10mg): Lactose monohydrate, Hypromellose 2910 (E464). Titanium Dioxide (E171), Macrogol 4000 (E1521).

### **What [Product Name] looks like and contents of the pack**

Rosuvastatin / Ezetimibe Film Coated Tablets, 5 mg / 10 mg: Light yellow, round, biconvex film coated tablets with a diameter of 10mm approximately and "EL 5" embossed on one side

Rosuvastatin / Ezetimibe Film Coated Tablets, 10 mg / 10 mg: Beige, round, biconvex film coated tablets with a diameter of 10mm approximately and "EL 4" embossed on one side

Rosuvastatin / Ezetimibe Film Coated Tablets, 20 mg / 10 mg: Yellow, round, biconvex film coated tablets with a diameter of 10mm approximately and "EL 3" embossed on one side

Rosuvastatin / Ezetimibe Film Coated Tablets, 40 mg / 10 mg: White, round, biconvex film coated tablets with a diameter of 10mm approximately and "EL 2" embossed on one side

Packs of 30, 60 and 90 film coated tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

Aurora Biofarma Srl.  
Via Nicola Antonio Porpora 127  
20131 Milaan  
Italy

#### **Manufacturer:**

Elpen SA, 95, Marathonos avenue  
190 09 Pikermi - Attica  
Greece

Elpen Pharmaceutical Co., Inc.  
Zapani, Block 1048  
190 01 Keratea  
Greece

Rontis Hellas Medical and Pharmaceutical Products S.A.,  
PO BOX 3012 Larissa Industrial Area,  
Larissa, 41 500  
Greece

#### **In het register ingeschreven onder:**

Rozemib 5 mg/10 mg, filmomhulde tabletten	RVG 125900
Rozemib 10 mg/10 mg, filmomhulde tabletten	RVG 125902
Rozemib 20 mg/10 mg, filmomhulde tabletten	RVG 125903
Rozemib 40 mg/10 mg, filmomhulde tabletten	RVG 125904

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

The Netherlands:	Rozemib 5 mg/10 mg, filmomhulde tabletten
	Rozemib 10 mg/10 mg, filmomhulde tabletten
	Rozemib 20 mg/10 mg, filmomhulde tabletten
	Rozemib 40 mg/10 mg, filmomhulde tabletten
Italy:	Aurozeb 5mg/10mg Compresse Rivestite Con Film
	Aurozeb 10mg/10mg Compresse Rivestite Con Film
	Aurozeb 20mg/10mg Compresse Rivestite Con Film
	Aurozeb 40mg/10mg Compresse Rivestite Con Film

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