

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

### **Cholecomb calcium 10 mg/10 mg harde capsules Cholecomb calcium 20 mg/10 mg harde capsules**

rosuvastatin and ezetimibe

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

#### **1. What Cholecomb calcium is and what it is used for**

Cholecomb calcium contains two different active substances in one capsule. One of the active substances is rosuvastatin, belonging to the group of so-called statins, the other active substance is ezetimibe.

Cholecomb calcium 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.

Cholecomb calcium 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 Cholecomb calcium if you are already taking both rosuvastatin and ezetimibe at the same dose level.

Cholecomb calcium does not help you lose weight.

## 2. What you need to know before you take Cholecomb calcium

### Do not take Cholecomb calcium if you:

- 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).
- if you take a combination of sofosbuvir/velpatasvir/voxilaprevir (medicines used for viral infection of the liver called hepatitis C).
- take a medicine called ciclosporin (used for example, after organ transplants).
- are pregnant or breast-feeding. If you become pregnant while taking Cholecomb calcium stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Cholecomb calcium by using suitable contraceptive measures

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

### Warnings and precautions

Talk to your doctor or pharmacist before taking Cholecomb calcium 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 Cholecomb calcium to suit you.
- take medicines used to fight infections, including HIV or hepatitis C infection e.g. lopinavir/ritonavir and/or atazanavir see “Other medicines and Cholecomb calcium”.
- have severe respiratory failure.
- take other medicines called fibrates to lower your cholesterol. See “Other medicines and Cholecomb calcium”.
- regularly drink large amounts of alcohol.
- have thyroid gland that is not working properly (hypothyroidism).
- are more than 70 years old (as your doctor needs to choose the right dose of Cholecomb calcium 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>.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with rosuvastatin treatment. Stop using Cholecomb calcium and seek medical attention immediately if you notice any of the symptoms described in section 4.

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 Cholecomb calcium is not recommended in children and adolescents under the age of 18 years.

### **Other medicines and < Product name >**

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

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 Cholecomb calcium 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 Cholecomb calcium), 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 also used to lower cholesterol), because it affects the way ezetimibe works.
- Regorafenib (used to treat cancer).
- Darolutamide (used to treat cancer).
- Any of the following medicines used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (see Warnings and precautions): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
- 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).

If you go into hospital or receive treatment for another condition, tell the medical staff that you are taking Cholecomb calcium.

**Pregnancy and breast-feeding**

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

Do not take Cholecomb calcium, if you are breast-feeding, because it is not known if the medicine is passed into breast milk.

**Driving and using machines**

Cholecomb calcium 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 Cholecomb calcium. If you get dizzy, talk to your doctor before driving or using machines.

**Cholecomb calcium contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.

**3. How to take Cholecomb calcium**

Always take 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 Cholecomb calcium.

The recommended daily dose for adults is one capsule of the given strength.

**Take Cholecomb calcium once daily.**

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

Take your medicine at the same time every day.

Cholecomb calcium 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 Cholecomb calcium of the appropriate strength is possible.

**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 take more Cholecomb calcium than you should**

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

**If you forget to take Cholecomb calcium**

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 taking Cholecomb calcium**

Talk to your doctor if you want to stop taking Cholecomb calcium. Your cholesterol levels might increase again if you stop taking Cholecomb calcium.

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 Cholecomb calcium and seek medical help immediately if you experience any of the following:**

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

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

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

- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- Erythema multiforme.

(life-threatening allergic reactions affecting the skin and mucous membranes).

#### Other possible side effects

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

- 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.
- Abdominal pain (stomach ache)
- Diarrhoea
- Flatulence (excess gas in the intestinal tract)
- Feeling tired
- Elevations in some laboratory blood tests of liver function (transaminases)

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

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

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

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

- 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 (frequency cannot be estimated from the available data)**

- 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 abdominal pain, 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 Cholecomb calcium**

Store below 30°C.

Store in the original package in order to protect from light and moisture.

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

Do not use this medicine after the expiry date (EXP) which is stated on the carton box and the blister. 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 Cholecomb calcium contains**

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

Cholecomb calcium 10 mg/10 mg hard capsules

Each capsule contains 10 mg of rosuvastatin (as rosuvastatin calcium) and 10 mg of ezetimibe.

Cholecomb calcium 20 mg/10 mg hard capsules

Each capsule contains 20 mg rosuvastatin (as rosuvastatin calcium) and 10 mg of ezetimibe.

The other ingredients are:

#### *Core*

Silicified microcrystalline cellulose {microcrystalline cellulose (E 460) and colloidal anhydrous silica (E 551)}, Magnesium stearate (E 572), colloidal anhydrous silica (E 551), povidone K-25 (E 1201), croscarmellose sodium (E 468), microcrystalline cellulose (E 460), mannitol (E 421), sodium laurilsulfate (E 514), low-substituted hydroxypropyl cellulose (E 463)

#### *Capsule shell*

Cholecomb calcium 10 mg/10 mg hard capsules:

Cap and body: Yellow iron oxide (E 172), Titanium dioxide (E 171), Gelatin

Cholecomb calcium 20 mg/10 mg hard capsules:

Cap: Red iron oxide (E 172), Titanium dioxide (E 171), Yellow iron oxide (E 172), Gelatin

Body: Yellow iron oxide (E 172), Titanium dioxide (E 171), Gelatine

### **What Cholecomb calcium looks like and contents of the pack**

Cholecomb calcium 10 mg/10 mg hard capsules: unmarked self-closing Coni Snap type, hard gelatine capsule with yellow coloured cap and yellow coloured body.

Cholecomb calcium 20 mg/10 mg hard capsules: unmarked self-closing Coni Snap type, hard gelatine capsule with caramel coloured cap and yellow coloured body.

Packs of 10, 28, 30, 56, 60, 90 hard capsules in cold blister (OPA/AL/PVC//Al) put into folded cardboard box and Patient Information Leaflet.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Egis Pharmaceuticals PLC  
1106 Boedapest, Keresztúri út 30-38.

Hongarije

**Manufacturers**

Egis Pharmaceuticals PLC  
1165 Boedapest, Bökényföldi út 118-120.  
Hongarije

Egis Pharmaceuticals PLC  
9900 Körmend, Mátyás király u. 65.  
Hongarije

**Dit geneesmiddel in ingeschreven onder:**

Cholecomb calcium 10 mg/10 mg harde capsules                      RVG 120478  
Cholecomb calcium 20 mg/10 mg harde capsules                      RVG 120484

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

<b>Country</b>	<b>Invented name</b>
The Netherlands	Cholecomb calcium 10 mg/10 mg harde capsules Cholecomb calcium 20 mg/10 mg harde capsules
Czech Republic	Delipid Duo
Romania	Lipocomb Calciu 10 mg/10 mg capsule Lipocomb Calciu 20 mg/10 mg capsule
Slovakia	Lipocomb Neo

**Deze bijsluiter is voor het laatst goedgekeurd in augustus 2021.**