

**Package leaflet: Information for the patient**  
**Rosuvastatin Zentiva 5 mg film-coated tablets**  
**Rosuvastatin Zentiva 10 mg film-coated tablets**  
**Rosuvastatin Zentiva 20 mg film-coated tablets**  
**Rosuvastatin Zentiva 40 mg film-coated tablets**

**rosuvastatin**

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

**1. What Rosuvastatin Zentiva is and what it is used for**

The name of your medicine is Rosuvastatin Zentiva 5 mg, 10 mg, 20 mg or 40 mg film-coated Tablets (referred to as Rosuvastatin Zentiva throughout this leaflet). Rosuvastatin Zentiva belongs to a group of medicines called statins.

You have been prescribed Rosuvastatin Zentiva because:

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke. Rosuvastatin Zentiva is used in adults, adolescents and children 6 years or older to treat high cholesterol.
- You have been advised to take a statin, because changing your diet and doing more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol lowering diet and exercise while you are taking Rosuvastatin Zentiva.

Or

- You have other factors that increase your risk of having a heart attack, stroke or related health problems.

Heart attack, stroke and other problems can be caused by a disease called atherosclerosis. Atherosclerosis is due to build-up of fatty deposits in your arteries.

**Why it is important to keep taking Rosuvastatin Zentiva**

Rosuvastatin Zentiva is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol.

There are different types of cholesterol found in the blood – “bad” cholesterol (LDL-C) and “good” cholesterol (HDL-C).

- Rosuvastatin Zentiva can reduce the “bad” cholesterol and increase the “good” cholesterol.
- It works by helping to block your body’s production of “bad” cholesterol. It also improves your body’s ability to remove it from your blood.

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.

You need to **keep taking Rosuvastatin Zentiva**, even if it has got your cholesterol to the right level, because **it prevents your cholesterol levels from creeping up again** and causing build-up of fatty deposits. However, you should stop if your doctor tells you to do so, or you have become pregnant.

## **2. What you need to know before you take Rosuvastatin Zentiva**

### **Do not take Rosuvastatin Zentiva if you**

- are allergic to rosuvastatin or any of the other ingredients of this medicine (listed in section 6).
- are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin Zentiva, stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin Zentiva by using suitable contraception.
- have liver disease.
- have severe kidney problems.
- have repeated or unexplained muscle aches or pains.
- take a drug combination of sofosbuvir/velpatasvir/voxilaprevir (used for viral infection of the liver called hepatitis C).
- take a drug called ciclosporin (used, for example, after organ transplants).

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

### **In addition, do not take Rosuvastatin Zentiva 30 mg or 40 mg (the highest doses) if**

- you have moderate kidney problems (if in doubt, please ask your doctor).
- your thyroid gland is not working properly.
- you have had any 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.
- you regularly drink large amounts of alcohol.
- you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- you take other medicines called fibrates to lower your cholesterol.

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Rosuvastatin Zentiva if

- you have problems with your kidneys.
- you have problems with your liver.
- you 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.
- you regularly drink large amounts of alcohol.
- your thyroid gland is not working properly.
- you have severe respiratory failure.
- you take other medicines called fibrates to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.

- you take medicines used to treat the HIV infection e.g. ritonavir with lopinavir and/or atazanavir, please see “Other medicines and Rosuvastatin Zentiva”.
- 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 Rosuvastatin Zentiva can lead to serious muscle problems (rhabdomyolysis), please see section “Other medicines and Rosuvastatin Zentiva”.
- if you are over 70 (as your doctor needs to choose the right start dose of Rosuvastatin Zentiva to suit you).
- if you are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of Rosuvastatin Zentiva to suit you.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Rosuvastatin Zentiva or other related medicines.
- if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).

If any of the above applies to you (or if you are not sure) **do not take Rosuvastatin Zentiva 30 mg and 40 mg (the highest doses) and check with your doctor or pharmacist before you actually start taking any dose of Rosuvastatin Zentiva.**

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 usually carry out this blood test (liver function test) before and during treatment with Rosuvastatin Zentiva.

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.

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

#### **Children and adolescents**

- If the patient is under 6 years old: Rosuvastatin Zentiva should not be given to children younger than 6 years.
- If the patient is below 18 years of age: The Rosuvastatin Zentiva 30 mg and 40 mg tablet is not suitable for use in children and adolescents below 18 years of age.

#### **Other medicines and Rosuvastatin Zentiva**

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).
- Darolutamide (used to treat cancer).
- Regorafenib (used to treat cancer).
- Warfarin, clopidogrel or ticagrelor (or any other drug used for thinning the blood).
- Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe).
- Indigestion remedies (used to neutralise acid in your stomach).
- Erythromycin (an antibiotic).
- Fusidic acid (an antibiotic – please see below and section “Warnings and precautions”).

- An oral contraceptive (the pill).
- Hormone replacement therapy.
- Capmatinib (used to treat cancer).
- Fostamatinib (used to treat low platelet counts).
- Febuxostat (used to treat and prevent high blood levels of uric acid).
- Teriflunomide (used to treat multiple sclerosis).
- Any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see section “Warnings and precautions”): Ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
- Roxadustat (used to treat anaemia in patients with chronic kidney disease),
- Tafamidis (used to treat a disease called transthyretin amyloidosis).

The effects of these medicines could be changed by Rosuvastatin Zentiva or they could change the effects of Rosuvastatin Zentiva.

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 Rosuvastatin Zentiva.

Taking Rosuvastatin Zentiva with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

### **Pregnancy, breast-feeding and fertility**

Do not take Rosuvastatin Zentiva if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin Zentiva stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin Zentiva by using suitable contraception.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Most people can drive a car and operate machinery while using Rosuvastatin Zentiva – it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin Zentiva .

If you feel dizzy, consult your doctor before attempting to drive or use machines.

### **Rosuvastatin Zentiva contains lactose and sodium**

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

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially “sodium-free”.

### **3. How to take Rosuvastatin Zentiva**

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 in adults**

If you are taking Rosuvastatin Zentiva for high cholesterol

##### *Starting dose*

Your treatment with Rosuvastatin Zentiva must start with the 5 mg or the 10 mg dose, even if you have taken a higher dose of a different statin before.

Administration of a 5 mg dose can be achieved by halving a 10 mg tablet with the score line.

Rosuvastatin Zentiva 10 mg film-coated tablets: The tablet can be divided into equal doses.

The choice of your starting dose will depend upon:

- Your cholesterol level.
- The level of risk you have of experiencing a heart attack or stroke.
- Whether you have a factor that may make you more sensitive to possible side effects.

Please check with your doctor or pharmacist which starting dose of rosuvastatin will best suit you.

Your doctor may decide to give you the lowest dose (5 mg) if:

- You are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- You are over 70 years of age.
- You have moderate kidney problems.
- You are at risk of muscle aches and pains (myopathy).

#### Increasing the dose and maximum daily dose

Your doctor may decide to increase your dose. This is so that you are taking the amount of Rosuvastatin Zentiva that is right for you. If you started with a 5 mg dose, your doctor may decide to increase this to 10 mg, then 15 mg, then 20 mg, then 30 mg and then 40 mg if necessary. If you started on 10 mg, your doctor may decide to double this to 20 mg, then increase it to 30 mg and then 40 mg if necessary. There will be a gap of 4 weeks between every dose adjustment. The maximum daily dose of Rosuvastatin Zentiva 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.

#### If you are taking Rosuvastatin Zentiva to reduce your risk of having a heart attack, stroke or related health problems:

The recommended dose is 20 mg daily. However, your doctor may decide to use a lower dose if you have any of the factors mentioned above.

#### **Use in children and adolescents aged 6 – 17 years**

The dose range in children and adolescents aged 6 to 17 years is 5 – 20 mg once daily. The usual start dose is 5 mg per day and your doctor may gradually increase your dose to find the right amount of Rosuvastatin Zentiva for you. The maximum daily dose of Rosuvastatin Zentiva is 10 mg or 20 mg for children aged 6 – 17 years depending on your underlying condition being treated. Take your dose once a day. Rosuvastatin Zentiva 40 mg tablets should not be used by children.

#### **Taking your tablets**

Swallow each tablet whole with a drink of water.

Take Rosuvastatin Zentiva once daily. You can take it at any time of the day with or without food.

Try to take your tablet at the same time every day to help you to remember it.

#### **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.

Your doctor may decide to increase your dose so that you are taking the amount of Rosuvastatin Zentiva that is right for you.

#### **If you take more Rosuvastatin Zentiva than you should**

Contact your doctor or nearest hospital for advice.

If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking Rosuvastatin Zentiva.

#### **If you forget to take Rosuvastatin Zentiva**

Don't worry, just 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 Rosuvastatin Zentiva**

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

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. They are usually mild and disappear after a short time.

**Stop taking Rosuvastatin Zentiva and seek medical help immediately** if you have any of the following allergic reactions (rare side effect):

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- Severe itching of the skin (with raised lumps).
- 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).

**Also, stop taking Rosuvastatin Zentiva and talk to your doctor immediately:**

- If you have any unusual aches or pains in your muscles which go on for longer than you might expect. Muscle symptoms are more common in children and adolescents than in adults. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life threatening muscle damage known as rhabdomyolysis.
- If you experience muscle rupture.
- If you have lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

The following adverse reactions have been reported with rosuvastatin (the active substance of product Rosuvastatin Zentiva):

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

- Headache.
- Stomach pain.
- Constipation.
- Feeling sick.
- Muscle pain.
- Feeling weak.
- Dizziness.
- An increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your Rosuvastatin Zentiva tablets (only Rosuvastatin Zentiva 40 mg).
- 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.

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

- Rash, itching or other skin reactions.
- An increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your Rosuvastatin Zentiva tablets (only Rosuvastatin Zentiva 5 mg, 10 mg, and 20 mg).

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

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). **If you think you are having an allergic reaction, then stop taking Rosuvastatin Zentiva** and seek medical help immediately.
- Muscle damage in adults – as a precaution, **stop taking Rosuvastatin Zentiva and talk to your doctor immediately if you have any unusual aches or pains** in your muscles which go on for longer than expected.
- A severe stomach pain (inflamed pancreas).
- Increase in liver enzymes in the blood.
- Bleeding or bruising more easily than normal due to low level of blood platelets.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

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

- Jaundice (yellowing of the skin and eyes).
- Hepatitis (an inflamed liver).
- Joint pain.
- 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):

- Depression.
- Muscle weakness that is constant.
- Tendon injury.
- Sleep disturbances, including insomnia and nightmares.
- Diarrhoea (loose stools).
- Cough.
- Shortness of breath.
- Oedema (swelling).
- Sexual difficulties.
- Breathing problems, including persistent cough and/or shortness of breath or fever.
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

### **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 HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Rosuvastatin Zentiva**

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 blister after “EXP”. The expiry date refers to the last day of that month.

Store below 25°C in the original package in order to protect from light and moisture.

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 Rosuvastatin Zentiva contains**

The active substance is rosuvastatin.

Each film-coated tablet contains 5 mg, 10 mg, 20 mg or 40 mg rosuvastatin as rosuvastatin calcium.

The other ingredients are: Tablet core: Lactose monohydrate, Cellulose, microcrystalline, Croscarmellose sodium, Silica colloidal anhydrous, Magnesium stearate. Coating layer: Hypromellose, Macrogol, Titanium dioxide (E171), Talc. Rosuvastatin Zentiva 10 mg, 20 mg and 40 mg also contains Iron oxide red (E172).

### **What Rosuvastatin Zentiva looks like and contents of the pack**

Rosuvastatin Zentiva 5 mg film-coated tablets: White to off-white, film-coated, round tablet with diameter approx. 5 mm.

Rosuvastatin Zentiva 10 mg film-coated tablets: Light pink, film-coated, oval, biconvex tablet with score line on one side with length approx. 9 mm and width approx. 5 mm.

Rosuvastatin Zentiva 20 mg film-coated tablets: Pink, film-coated, oval, biconvex tablet with length approx. 11 mm and width approx. 6 mm.

Rosuvastatin Zentiva 40 mg film-coated tablets: Dark pink, film-coated, oval, biconvex tablet with length approx. 14 mm and width approx. 7 mm.

Rosuvastatin Zentiva 5, 10, 20, 40 mg is available in blisters containing 14, 15, 28, 30, 56, 60, 84, 90, 98, 100 film-coated tablets. Not all pack sizes may be marketed.

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

Zentiva, k.s.

U Kabelovny 130, Dolní Měcholupy,

Prague 10, 102 37 Prague

Czech Republic

### **This medicine is authorised in the Member States of the European Economic Area under the following names:**

Portugal

Czech Republic, Italy

Denmark, Germany, Ireland, Latvia, Lithuania,

Norway, Sweden

Rosuvastatina ZenPrime

Rosucard

Rosuvastatin Zentiva

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