

**Package leaflet: Information for the patient**  
**Rosuvastatin Teva 5 mg film-coated tablets**  
**Rosuvastatin Teva 10 mg film-coated tablets**  
**Rosuvastatin Teva 20 mg film-coated tablets**  
**Rosuvastatin Teva 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 Teva is and what it is used for
2. What you need to know before you take Rosuvastatin Teva
3. How to take Rosuvastatin Teva
4. Possible side effects
5. How to store Rosuvastatin Teva
6. Contents of the pack and other information

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

Rosuvastatin Teva belongs to a group of medicines called statins.

**You have been prescribed Rosuvastatin Teva because:**

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke. Rosuvastatin Teva 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 taking 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 Teva.

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 is it important to keep taking Rosuvastatin Teva?**

Rosuvastatin Teva 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 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 Teva**, 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 Teva**

### **Do not take Rosuvastatin Teva**

- **If you are allergic to rosuvastatin** or any of the other ingredients of this medicine (listed in section 6)
- **If you are pregnant or breast-feeding.** If you become pregnant while taking Rosuvastatin Teva **stop taking it immediately and tell your doctor.** Women should avoid becoming pregnant while taking Rosuvastatin Teva by using suitable contraception
- **If you have liver disease**
- **If you have severe kidney problems**
- **If you have repeated or unexplained muscle aches or pains**
- **If you 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 Teva 40 mg film-coated tablets (the highest dose):**

- **If you have moderate kidney problems** (if in doubt, please ask your doctor)
- **If your thyroid gland is not working properly**
- **If 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
- **If you regularly drink large amounts of alcohol**
- **If you are of Asian origin** (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian)
- **If 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 Teva.

- **If you have problems with your kidneys**
- **If you have problems with your liver**
- **If 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
- **If you regularly drink large amounts of alcohol**
- **If your thyroid gland** is not working properly
- **If 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
- **If you take medicines used to treat the HIV or hepatitis C infection** e.g. ritonavir with lopinavir and/or atazanavir or simeprevir, please see **Other medicines and Rosuvastatin Teva**

- **If you take antibiotics containing fusidic acid.** If 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 Teva can lead to serious muscle problems (rhabdomyolysis).

### Children and adolescents

**If the patient is under 6 years old:** Rosuvastatin Teva **should not** be given to children younger than 6 years.

**If the patient is below 18 years of age:** Rosuvastatin Teva 40 mg film-coated tablets **are not suitable** for use in children and adolescents below 18 years of age.

- **If you are over 70** (as your doctor needs to choose the right start dose of Rosuvastatin Teva to suit you)
- **If you have severe respiratory failure**
- **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 Teva to suit you.

If any of the above applies to you (or if you are not sure):

- **Do not take Rosuvastatin Teva 40 mg film-coated tablets (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of Rosuvastatin Teva.**

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 Teva.

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.

### Other medicines and Rosuvastatin Teva

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

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

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

- ciclosporin (used for example, after organ transplants)
- warfarin or clopidogrel (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)
- an oral contraceptive (the pill)
- hormone replacement therapy
- anti-viral medications such as ritonavir with lopinavir and/or atazanavir or simeprevir (used to treat infections, including the HIV or hepatitis C infection - please see Warnings and precautions).

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

### Pregnancy and breast-feeding

**Do not take Rosuvastatin Teva** if you are pregnant or breast-feeding. If you become pregnant while taking Rosuvastatin Teva **stop taking it immediately** and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin Teva 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 Teva - it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin Teva. If you feel dizzy, consult your doctor before attempting to drive or use machines.

### **Rosuvastatin Teva contains lactose, sunset yellow and carmoisine**

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

The tablet coating for the 5 mg tablets contain sunset yellow FCF (E110) and for the 10 mg, 20 mg and 40 mg tablets it contains carmoisine (E122). These colouring agents may cause allergic reactions. For a full list of ingredients please see Contents of the pack and other information.

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

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

### **Usual doses in adults**

#### **If you are taking Rosuvastatin Teva for high cholesterol:**

##### **Starting dose**

Your treatment with Rosuvastatin Teva must start with the **5 mg or the 10 mg dose**, even if you have taken a higher dose of a different statin before. The choice of your start 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 start dose of Rosuvastatin Teva 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 Teva that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then 20 mg and then 40 mg if necessary. If you started on 10 mg, your doctor may decide to double this to 20 mg and then 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of Rosuvastatin Teva 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 Teva 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 usual start dose is 5 mg. Your doctor may increase your dose to find the right amount of Rosuvastatin Teva for you. The maximum daily dose of Rosuvastatin Teva is 10 mg for children aged 6 to 9 years and 20 mg for children aged 10 to 17 years. Take your dose once a day. Rosuvastatin Teva **40 mg** film-coated tablets **should not** be used by children.

### **Taking your tablets**

Swallow each tablet whole with a drink of water.

### **Take Rosuvastatin Teva 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 Teva that is right for you.

### **If you take more Rosuvastatin Teva 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 are taking Rosuvastatin Teva.

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

Do not 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 Teva**

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

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 Teva and seek medical help immediately** if you have any of the following allergic reactions:

- 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).

**Also, stop taking Rosuvastatin Teva 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*.

**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 Teva film-coated tablets (only Rosuvastatin Teva 40 mg film-coated tablets)
- 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 Teva film-coated tablets (only Rosuvastatin Teva 5 mg, 10 mg and 20 mg film-coated tablets).

**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 Teva and seek medical help immediately**
- Muscle damage in adults- as a precaution, **stop taking Rosuvastatin Teva 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.

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

- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Traces of blood in your urine
- Damage to the nerves of your legs and arms (such as numbness)
- Joint pain
- Memory loss
- Breast enlargement in men (gynaecomastia).

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

- Diarrhoea (loose stools)
- Stevens-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals)
- Cough
- 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.

### 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Rosuvastatin Teva

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.

Rosuvastatin Teva 5 mg film-coated tablets:  
Do not store above 25°C.

Rosuvastatin Teva 10 mg, 20 mg and 40 mg film-coated tablets:  
Do not store above 30°C.

Keep the blister in the outer carton in order to protect from moisture and light.

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 Teva contains

The active substance is rosuvastatin (as rosuvastatin calcium).

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

The other ingredients are:

#### *Tablet core:*

Cellulose, microcrystalline (Avicel PH-112)  
Crospovidone (Type A) (Kollidon CL)  
Lactose anhydrous  
Povidone (PVP K-30)  
Sodium stearyl fumarate (PRUV).

#### *Film-coating:*

Rosuvastatin Teva 5 mg film-coated tablets:  
**Opadry II 85F23426 Orange**  
(Poly-vinyl alcohol) - partly hydrolyzed  
Titanium dioxide (E171)  
Macrogol 3350 (polyethylene glycol)  
Talc (E553b)  
Iron oxide yellow (E172)  
Iron oxide black (E172)  
Sunset yellow FCF (E110, FD&C Yellow #6)

Rosuvastatin Teva 10 mg, 20 mg and 40 mg film-coated tablets:

**Opadry II 85F24155 Pink**

(Poly-vinyl alcohol) - partly hydrolyzed

Titanium dioxide (E171)

Macrogol 3350 (polyethylene glycol)

Talc (E553b)

Iron oxide yellow (E172)

Iron oxide red (E172)

Carmoisine (E122, aluminium lake)

Indigotine (E132, Indigo carmine aluminium lake FD&C blue #2)

**What Rosuvastatin Teva looks like and contents of the pack**

Rosuvastatin Teva 5 mg tablet: Orange, round, standard convex film-coated tablet, debossed with "N" on one side and with "5" on the other side of the tablet.

Rosuvastatin Teva 10 mg tablet: Light pink to pink, round, standard convex film-coated tablet, debossed with "N" on one side and with "10" on the other side of the tablet.

Rosuvastatin Teva 20 mg tablet: Light pink to pink, round, standard convex film-coated tablet, debossed with "N" on one side and with "20" on the other side of the tablet.

Rosuvastatin Teva 40 mg tablet: Light pink to pink, oval shaped film-coated tablet, debossed with "N" on one side and with "40" on the other side of the tablet.

Rosuvastatin Teva comes in blister packs of: 14, 14 x 1, 15, 15 x 1, 20, 20 x 1, 28, 28 x 1, 30, 30 x 1, 56, 56 x 1, 60, 60 x1, 90, 90 x 1, 98, 98 x 1, 100 and 100 x 1 film-coated tablets in a carton.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

Teva Pharma B.V.,  
Swensweg 5,  
2031GA Haarlem,  
The Netherlands

**Manufacturer**

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Blaubeuren, Germany

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

Austria - Rosuvastatin Teva 5 mg, 10 mg, 20 mg & 40 mg Filmdabletten  
Bulgaria - Rosuvastatin Teva 10 mg & 20 mg & film-coated tablets  
Czech Republic - Rosuvastatin Teva 10 mg, 20 mg & 40 mg  
Denmark - Rosuvastatin Teva  
Estonia - Rosuvastatin Teva 10 mg & 20 mg  
Hungary - Rosuvastatin Teva 5 mg, 10 mg, 20 mg & 40 mg filmtableta  
Ireland - Rosuvastatin Teva 5 mg, 10 mg, 20 mg & 40 mg film-coated tablets  
Lithuania - Rosuvastatin Teva 10 mg & 20 mg plevele dengtos tabletes  
Poland - Rosuvastatin Teva  
Portugal - Rosuvastatina Qritou 5 mg, 10 mg, 20 mg & 40 mg comprimidos revestidos por película  
Slovenia - Rosuvastatin Teva 5 mg, 10 mg, 20 mg & 40 mg filmsko obložene tablete  
Spain - Rosuvastatina Belmac 5 mg, 10 mg, 20 mg & 40 mg comprimidos recubiertos con película EFG

**This leaflet was last revised in 03/2017**