Package leaflet: Information for the user

Rosuvastatin 5 mg Film-coated tablets Rosuvastatin 10mg Film-coated tablets Rosuvastatin 20mg Film-coated tablets Rosuvastatin 40mg Film-coated tablets (Rosuvastatin)

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

- Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor of
- 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 Film-coated tablets are and what they are used for
- 2. What you need to know before you take Rosuvastatin Filmcoated tablets
- How to take Rosuvastatin Film-coated tablets
- Possible side effects
- How to store Rosuvastatin Film-coated tablets Contents of the pack and other information
- 1. What Rosuvastatin Film-coated Tablets are and what they are used for

Rosuvastatin Film-coated tablets belong to a group of medicines called statins

You have been prescribed Rosuvastatin Film-coated tablets because:

You have a high cholesterol level. This means you are at risk from a heart attack or stroke. 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 cholesterollowering diet and exercise while you are taking Rosuvastatin Filmcoated tablets

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 Film-coated

Rosuvastatin Film-coated tablets are 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 Film-coated tablets 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 fee 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

You need to keep taking Rosuvastatin Film-coated tablets, even if they have 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 Film-coated Tablets

## Do not take Rosuvastatin Film-coated tablets

- 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 Film-coated tablets stop taking them immediately and tell your doctor. Women should avoid becoming pregnant while taking Rosuvastatin Filmcoated tablets by using suitable contraception
- If you have liver disease If you have severe kidney problems
- · If you have repeated or unexplained muscle aches or
- If you take a drug called ciclosporin (used, for example after organ transplants)
- if you are taking or, in the last 7 days, have taken or been given a medicine called fusidic acid (used to treat bacteria

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 40mg (the highest dose) Film-coated tablets

- 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 aking other cholesterol-lowering medicines.
- If you regularly drink large amounts of alcohol If you are of Asian origin (Japanese, Chinese, Filipino,
- etnamese, Korean and Indian) • If you take other medicines called fibrates to lower your

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

Warnings and precautions

Pharma Code:

**Revision date:** 

Talk to your doctor or pharmacist before taking Rosuvastatin Film

- 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 fight the HIV infection e.g. ritonavir with lopinavir and/or atazanavir, please see Other medicines and Rosuvastatin Film-coated Tablets.
- If you are over 70 (as your doctor needs to choose the right start dose of Rosuvastatin Film-coated tablets to suit you)
- If you have severe respiratory failure
- 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 Film-coated

#### Children and adolescents

- If the patient is under 10 years old : Rosuvastatin Filmcoated tablets should not be given to children younger than
- If the patient is below 18 years of age: The Rosuvastatin Film-coated 40mg tablet is not suitable for use in children and adolescents below 18 years of age.

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

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

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 Film-coated tablets.

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

 $Other \, medicines \, and \, Rosuva statin \, Film\text{-}coated \, tablets$ 

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)
- warfarin (or any other drug used for thinning the blood) fibrates (such as gemfibrozil, fenofibrate, nicotinic acid) or any
- other medicine used to lower cholesterol (such as ezetimibe) indigestion remedies (used to neutralise acid in your stomach)
- erythromycin or fusidic acid (used to treat bacterial infections). Do not take fusidic acid while using this medicine. Also see
- section Do not take Rosuvastatin Film-coated tablets eltrombopag (used to treat low platelet counts)
- dronedarone (medicines for an irregular heartbeat) rifampin (medicine used to treat tuberculosis)
- ketoconazole, fluconazole, itraconazole (medicines used to
- treat fungal infections) an oral contraceptive (the pill), hormone replacement therapy
- ritonavir with lopinavir and/or atazanavir, darunavir/ritonavir;

tipranavir/ritonavir, fosamprenavir/ritonavir (used to treat the HIV infection- please see Warnings and precautions) Also inform your doctor if you are taking medicines such as

silymarin, aleglitazar or baicalin. The effects of these medicines could be changed by Rosuvastatin

Film-coated tablets or they could change the effects of Rosuvastatin Film-coated tablets

## Pregnancy and Breast-feeding

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

Ask your doctor or pharmacist for advice before taking any

## Driving and using machines

Most people can drive a car and operate machinery while using Rosuvastatin Film-coated tablets - it will not affect their ability. However, some people feel dizzy during treatment with Rosuvastatin Film-coated tablets. If you feel dizzy, consult your doctor before attempting to drive or use machines.

## Rosuvastatin Film-coated tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking Rosuvastatin Film-coated tablets

For a full list of ingredients please see Contents of the pack and

other information.

3. How to take Rosuvastatin Film-coated Tablets

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

Recommended doses in adults If you are taking Rosuvastatin Film-coated tablets for high

## Starting dose

Your treatment with Rosuvastatin Film-coated tablets must start with the 5mg or the 10mg 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

Please check with your doctor or pharmacist which start dose of Rosuvastatin Film-coated tablets 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 Film-coated tablets 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 Film-coated tablets 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 Film-coated tablets to reduce your risk of having a heart attack, stroke or related health problems:

The recommended dose is 20mg 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 10-17 years

The recommended start dose is 5mg. Your doctor may increase your dose to find the right amount of Rosuvastatin Film-coated tablets for you. The maximum daily dose of Rosuvastatin Filmcoated tablets is 20mg. Take your dose once a day. Rosuvastatin Film-coated 40mg tablets should not be used by children

### Taking your tablets

Swallow each tablet whole with a drink of water

Take Rosuvastatin Film-coated tablets 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 Film-coated tablets that is right for you

## If you take more Rosuvastatin Film-coated tablets than you

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 Film-coated

#### If you forget to take Rosuva statin Film-coated tablets 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 Film-coated tablets Talk to your doctor if you want to stop taking Rosuvastatin Filmcoated tablets. Your cholesterol levels might increase again if you

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

stop taking Rosuvastatin Film-coated tablets

## 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 Film-coated tablets and seek medical help immediately if you have any of the following

- · 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 Film-coated tablets 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

Tell your doctor as soon as possible if you develop any of the

and rarely these have gone on to become a potentially life

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

threatening muscle damage known as rhabdomyolysis

- Headache
- Stomach pain Constipation

Feeling weak

- Feeling sick Muscle pain
- 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 Film-coated tablets (only Rosuvastatin 40mg Film-coated tablets)
- Diabetes. This is more likely if you have high levels of sugar and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking

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

- Rash, itching, hives
- 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 Film-coated tablets (only Rosuvastatin 5 mg, 10 mg and 20 mg Film-coated tablets).

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

- Severe allergic reaction signs includes 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 Film-coated tablets and seek medical
- help immediately Muscle damage in adults - as a precaution, stop taking Rosuvastatin 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 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 A general degeneration of peripheral nerves that spreads
- towards the centre of the body (Polyneuropathy) Joint pain
- Memory loss
- Breast enlargement in men (gynecomastia)

### Not known (frequency cannot be estimated from the available

- Damage to the nerves of your legs and arms (Peripheral
- neuropathy)
- Diarrhoea (loose stools) Steven-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 disorder or rupture
- 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; e-mail: medsafety@hpra.ie

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

### 5. How to store Rosuvastatin Film-coated Tablets

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 label after Exp. The expiry date refers to the last day of

Store below 30°C, in original packaging.

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 Film-coated tablets contains: The active substance in Rosuvastatin Film-coated tablets is Rosuvastatin. Rosuvastatin Film-coated tablets contain Rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg  $\,$ of Rosuvastatin. The other ingredients are: lactose monohydrate. microcrystalline cellulose, crospovidone, magnesium stearate, sodium citrate, opadry yellow (hypromellose, titanium dioxide (E171), macrogol 400, iron oxide yellow (E172)), opadry pink (hypromellose, titanium dioxide, macrogol 400, iron oxide red

### What Rosuvastatin Film-coated tablets look like and contents of the pack

Rosuvastatin 5 mg Film-coated tablets: Light yellow to yellow coloured round film coated tablets 'RT 1' debossed on one side and plain on other side.

Rosuvastatin 10 mg Film-coated tablets: Light pink to pink coloured round film coated tablets 'RT 2' debossed on one side and plain on other side.

Rosuvastatin 20 mg Film-coated tablets: Light pink to pink

coloured round film coated tablets 'RT 3' debossed on one side

Rosuvastatin 40 mg Film-coated tablets: Light pink to pink coloured oval film coated tablets 'RT 4' debossed on one side and plain on other side.

and plain on other side.

Rosuvastatin Film-coated tablets is available in packs of 7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98 and 100 tablets.

### Marketing Authorisation Holder and Manufacturer Ranbaxy Ireland Ltd., Spafield, Cork Road, Cashel, Co. Tipperary,

This medicinal product is authorised in the Member States of

the EEA under the following names

Rosuvistat 5/10/20/40 mg film-coated tablets Cresagen 5 mg / 10 mg / 20 mg / 40 mg potahované

EL VENEX 5/10/20/40 mg επικαλυμμένα με λεπτό υμένιο δισκία ROSUVASTATINA RANBAXY 5-10-20MG COMPRIMIDOS RECOBIERTOS

Rosuvastatin 5 mg/10mg/20mg/40mg film-coated tablets

Rosuvastatin Ranbaxy Cresagen 5/10/20/40 mg filmtabletta HU This leaflet was last revised in July 2015

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RANBAXY (PACKAGING DEVELOPMENT PAONTA)

Description: **ROSUVASTATIN TABS (Lit.)** Market: Ireland **Dimensions:** 140 x 400 mm (Folded Size: 140 x 200 mm) **New SAP Code:** 5118858 Old SAP Code: 5108477

> 18858 08.07.2015

**Black** 

**Colours** 

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