

## Package leaflet: Information for the user

**Rosuvastatine Torrent 5 mg, filmomhulde tabletten**  
**Rosuvastatine Torrent 10 mg, filmomhulde tabletten**  
**Rosuvastatine Torrent 20 mg, filmomhulde tabletten**  
**Rosuvastatine Torrent 40 mg, filmomhulde tabletten**  
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 [Product name] is and what it is used for
2. What you need to know before you take [Product name]
3. How to take [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] belongs to a group of medicines called statins.

#### **You have been prescribed [Product name] because:**

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke. [Product name] 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 [Product name].

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 [Product name]**

[Product name] 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).

- [Product name] 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 [Product name]**, 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 [Product name]

### Do not take [Product name]

- **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 [Product name] **stop taking it immediately and tell your doctor**. Women should avoid becoming pregnant while taking [Product name] 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 combination of sofosbuvir/velpatasvir/voxilaprevir** (used for viral infection of the liver called hepatitis C).
- **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 [Product name] 40 mg (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 [Product name]:

- **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 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).

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- **If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking [Product name] or other related medicines.**
- **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 infection** e.g. ritonavir with lopinavir and/or atazanavir, please see “**Other medicines and [Product name]**”.
- **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 [Product name] can lead to serious muscle problems (rhabdomyolysis), please see “**Other medicines and [Product name]**”.
- **If you are over 70** (as your doctor needs to choose the right start dose of [Product name] 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 [Product name] to suit you.

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

**Do not take [Product name] 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of [Product name].**

Serious skin reactions including Stevens-Johnsons syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with rosuvastatin treatment. Stop using [Product name] 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 usually carry out this blood test (liver function test) before and during treatment with [Product name].

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**

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

#### **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),
- 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 “Warnings and precautions”),
- an oral contraceptive (the pill),
- regorafenib (used to treat cancer),

- darolutamide (used to treat cancer),
- capmatinib (used to treat cancer),
- hormone replacement therapy,
- 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 Warnings and precautions): ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir

The effects of these medicines could be changed by [Product name] or they could change the effect of [Product name].

**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.**

### **Pregnancy and breastfeeding**

**Do not take [Product name]** if you are pregnant or breastfeeding. 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 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 [Product name] – it will not affect their ability. However, some people feel dizzy during treatment with [Product name]. If you feel dizzy, consult your doctor before attempting to drive or use machines.

### **[Product name] contains 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.

### **[Product name] contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

## **3. How to take [Product name]**

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 [Product name] for high cholesterol:**

#### **Starting dose**

Your treatment with [Product name] 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 [Product name] 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 [Product name] 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 [Product name] 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 [Product name] 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 to 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 [Product name] for you. The maximum daily dose of [Product name] is 10 or 20 mg for children aged 6 to 17 years depending on your underlying condition being treated. Take your dose once a day. [Product name] **40 mg** tablet should **not** be used by children.

#### **Taking your tablets**

Swallow each tablet whole with a drink of water.

[Product name] 10 mg, 20 mg and 40 mg can be divided in equal doses.

**Take [Product name] 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 [Product name] that is right for you.

#### **If you take more [Product name] 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 [Product name].

#### **If you forget to take [Product name]**

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

##### **Stop taking [Product name] 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).
- 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 [Product name] 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).

##### **Possible side effects**

**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 [Product name] tablets (only [Product name] 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 [Product name] tablets (only [Product name] 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 [Product name] and seek medical help immediately**
- Muscle damage in adults – as a precaution, **stop taking [Product name] 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)
- 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)
- 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
- Peripheral neuropathy (An unusual tingling, weakness or pain in your hands or feet)
- 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.

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### **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 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]**

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

HDPE bottle:

Use within 90 days after first opening.

This medicinal product does not require any special storage conditions.

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 substance is rosuvastatin.  
Each film-coated tablet contains 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, hypromellose, triacetin and titanium dioxide (E 171).  
[Product name] 5 mg tablets also contain ferric oxide yellow (E 172).  
[Product name] 10, 20 and 40 mg tablets also contain ferric oxide red (E 172).

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

#### **[Product name] 5 mg**

[Product name] 5 mg are yellow coloured, round, biconvex, film-coated tablets with a diameter of approx. 5.7 mm, debossed with “135” on one side and “5” on the other side.

#### **[Product name] 10 mg**

[Product name] 10 mg are light pink coloured, round, biconvex, film-coated tablets with a diameter of approx. 7.5 mm, debossed with break line on both sides, separating “11” and “36” on one side and “10” on the other side.

#### **[Product name] 20 mg**

[Product name] 20 mg are light pink coloured, round, biconvex, film-coated tablets with a diameter of approx. 9.6 mm, debossed with break line on both sides, separating “11” and “37” on one side and “20” on the other side.

#### **[Product name] 40 mg**

[Product name] 40 mg are light pink coloured, oval shape, approx. 12.4 x 6.5 mm biconvex, bevelled edge, film-coated tablets, with break line on both sides.

[Product name] is available in

Aluminium/ OPA/Aluminium/PVC blister packs containing  
7, 14, 15, 20, 28, 30, 42, 50, 56, 60, 84, 90, 98, 100 or 200 tablets

HDPE bottles, neck finish with child resistant closure and with induction sealing wad containing  
30, 90 or 500 (hospital pack, for use on more than one patient) tablets

Not all pack sizes may be marketed.

### **Houder van de vergunning voor het in de handel brengen**

Torrent Pharma GmbH  
Südwestpark 50, 90449 Nürnberg  
Duitsland

### **Fabrikant**

Rosuvastatin Torrent 5/10/20/40 mg, filmomhulde tabletten, 5/10/20/40 mg, film-coated tablet – NL/H/2854/001-004/DC  
NL pl  
NL/p/003/17/12

Heumann Pharma GmbH & Co. Generica KG  
Südwestpark 50, 90449 Nürnberg  
Duitsland

Torrent Pharma (Malta) Ltd  
Central Business Centre, Level 2,  
Triq Hal Tarxien,  
Il-Gudja, GDJ 1907,  
Malta

**In het register ingeschreven onder**

Rosuvastatine Torrent 5 mg, filmomhulde tabletten	RVG 113086
Rosuvastatine Torrent 10 mg, filmomhulde tabletten	RVG 113087
Rosuvastatine Torrent 20 mg, filmomhulde tabletten	RVG 113088
Rosuvastatine Torrent 40 mg, filmomhulde tabletten	RVG 113089

**Dit geneesmiddel is in de Lidstaten van de EEA geautoriseerd onder de volgende namen:**

Nederland: Rosuvastatine Torrent 5/10/20/40 mg, filmomhulde tabletten  
Duitsland: Rosuvastatin Heumann 5/10/20/40 mg Filmtabletten

**Deze bijsluiter is voor de laatste keer goedgekeurd in februari 2024.**