

# ROTAQOR<sup>®</sup> FILM-COATED TABLETS

Consumer Medication Information Leaflet (RiMUP)

Atorvastatin (10mg, 20mg)

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## What is Rotaqor used for

You have been prescribed Rotaqor because either:

(a) You have a high cholesterol level. This means you are at risk of getting 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 cholesterol-lowering diet and exercise while you are taking Rotaqor.

Or

(b) You have other factors that increase your risk of getting a heart attack, stroke or related health problems.

## How Rotaqor works

Rotaqor belongs to a group of medicines called statins.

There are different types of cholesterol found in the blood, including – ‘bad’ cholesterol (LDL-C) and ‘good’ cholesterol (HDL-C).

- Rotaqor can reduce the ‘bad’ cholesterol and increase the ‘good’ cholesterol.
- It works by helping to block your body’s production of ‘bad’ cholesterol in the liver. 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 getting a heart attack, a stroke or related health problems

## Before you use Rotaqor

- When you must not use it

- If you are allergic (hypersensitive) to atorvastatin, or to any of the ingredients.
- If you have liver disease.
- If you have repeated or unexplained muscle aches or pains.
- If you are treated with hepatitis C antivirals (glecaprevir/pibrentasvir).

If you think any of the above situations applies to you do not take the tablets. Consult your doctor and take his/her advice.

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

## Pregnancy and breast-feeding

Do not take Rotaqor if you are pregnant or breast-feeding. If you become pregnant while taking Rotaqor, stop taking it immediately and tell your doctor.

Women should avoid becoming pregnant while taking Rotaqor by using suitable contraception.

Ask your doctor or pharmacist for advice before taking any medicine

- Before you start use it

You should check with your doctor before taking Rotaqor:

- If you have problems with your kidney.
- If your thyroid gland is not working properly.
- If you regularly drink large amounts of alcohol.
- If you take medicines used to fight the HIV infection (e.g. lopinavir/ritonavir).
- If you have severe respiratory failure.
- If you are over 70 years old.
- If you take other medicines called fibrates to lower your cholesterol.

- If you have diabetes.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including any you bought without a prescription.

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

- Ciclosporin (used for example, after organ transplants)
- Lopinavir/ritonavir (used to fight the HIV infection)
- Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe)
- antacids
- Erythromycin (an antibiotic)
- Warfarin (or any other drug used for thinning the blood)
- Oral contraceptive

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

Ask your doctor/ pharmacist if you are not sure.

## How to use Rotaqor

- How much to use

Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

## Usual doses in adults

For oral use.

The usual recommended starting dose of atorvastatin is 10 mg once daily. The dose range is 10 to 80 mg once daily, can be given any time of the day, with or without food.

The doctor will prescribe a dose that is individualized to your needs and condition.

Your doctor will choose your starting dose depending upon:

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

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- When to use it

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

- How long to use it

It is important to take your medicine every day. Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue taking this medicine.

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

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the nearest emergency department if you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

### While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Rotaqor.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Rotaqor to anyone

else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

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

### Side effects

Like all medicines, Rotaqor can cause side effects, although not everybody gets them.

### Infection and infestations

Common: Inflammation of the nasal cavities

### Blood and lymphatic system disorders

Rare: Low platelet levels

### Immune system disorders

Common: Allergic reactions  
Very rare: Life-threatening allergic reactions

### Metabolism and nutrition disorders

Common: High blood glucose levels  
Uncommon: Low blood glucose levels, weight gain, anorexia (an eating disorder)

### Psychiatric disorders

Uncommon: Nightmare, insomnia (difficulty sleeping)

### Nervous system disorders

Common: Headache  
Uncommon: Dizziness, tingling sensation, reduced sense of touch and sensation, distortion of sense of taste, memory loss  
Rare: Damage to nerves that is outside of the brain and spinal cord

### Eye disorders

Uncommon: Blurred vision  
Rare: Visual disturbance

### Ear disorders

Uncommon: Ringing in the ear  
Very Rare: Hearing loss

### Respiratory system disorders

Common: Throat pain, bleeding of nose

### Gastrointestinal disorders

Common: Constipation, flatulence, abdominal discomfort, nausea, diarrhoea  
Uncommon: Vomiting, upper and lower abdominal pain, belching, inflammation of pancreas

### Liver disorders

Uncommon: Hepatitis  
Rare: Decreased in bile flow  
Very rare: Liver failure

### Skin and subcutaneous tissue disorders

Uncommon: Itchiness, rash and hives, spot baldness  
Rare: Angioneurotic edema, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis

### Musculoskeletal and connective tissue disorders

Common: muscle pain, joint pain, pain in extremity, muscle spasms, joint swelling, back pain  
Uncommon: Neck pain, muscle fatigue  
Rare: Muscle damage, muscle inflammation, death of muscle fibres, tendon disorders, sometimes complicated by rupture  
Not known: Immune-mediated necrotising myopathy  
Very rare: Lupus-like syndrome

### Reproductive system disorders

Very rare: Enlargement of breast in men

### General disorders

Uncommon: Feeling of discomfort, weakness, chest pain, swelling of lower limbs, tiredness, fever

### Investigations

Common: Liver function test abnormal, blood creatinine kinase increased  
Uncommon: White blood cells urine positive

If you have muscle problems that do not go away after your doctor has told you to stop taking Rotaqor, please refer to your doctor. Your

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doctor may do further tests to diagnose the cause of your muscle problems.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and disposal of Rotaqor

### - Storage

Keep out of the reach and sight of children.

Do not use your medicine after the expiry date.

Store below 30°C in the original package in order to protect from moisture.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product description

### - What it looks like

#### Rotaqor 10 mg film coated tablet

White to almost white, round, biconvex film-coated tablets, debossed with “HLA 10” on one side.

#### Rotaqor 20 mg Film Coated Tablet

Light yellow, round biconvex film-coated tablets, debossed with “HLA 20” on one side.

### - Ingredients

#### Active ingredient

Each Rotaqor 10 mg film coated tablet contains 10 mg atorvastatin as atorvastatin calcium.

Each Rotaqor 20 mg film coated tablet contains 20 mg atorvastatin as

atorvastatin calcium.

### Inactive ingredients

#### Rotaqor 10 mg

Microcrystalline Cellulose  
Lactose Monohydrate  
Croscarmellose Sodium  
Hydroxypropyl Cellulose  
Polysorbate 80  
Magnesium Oxide  
Colloidal Anhydrous Silica  
Magnesium Stearate  
Hypromellose  
Titanium Dioxide  
Macrogol 6000  
Talc

#### Rotaqor 20 mg

Microcrystalline Cellulose  
Lactose Monohydrate  
Croscarmellose Sodium  
Hydroxypropyl Cellulose  
Polysorbate 80  
Magnesium Oxide  
Colloidal Anhydrous Silica  
Magnesium Stearate  
Hypromellose  
Titanium Dioxide  
Macrogol 6000  
Ferric oxide yellow  
Talc

### - MAL numbers

Rotaqor 10mg Film Coated Tablet:  
MAL09062160ACZ

Rotaqor 20mg Film Coated Tablet:  
MAL09062161ACZ

## Manufacturer

Novartis Pharmaceutical  
Manufacturing LLC  
Verovskova ulica 57,  
1000 Ljubljana, Slovenia

## Product registration holder

Sandoz Products Malaysia Sdn.  
Bhd.  
Unit 1202, Level 12, Uptown 1,  
No. 1, Jalan SS 21/58,  
Damansara Uptown, 47400 Petaling  
Jaya, Selangor, Malaysia

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October 2024

## Serial number

NPRA(R4/1)230719/00208