

PACKAGE LEAFLET: INFORMATION FOR THE USER
KOLROS™ 10 mg film-coated tablets
KOLROS™ 20 mg film-coated tablets
KOLROS™ 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.

What is in this leaflet:

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

1. What KOLROS™ is and what it is used for

KOLROS™ belongs to a group of medicines called statins.

You have been prescribed KOLROS™ 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 cholesterol-lowering diet and exercise while you are taking KOLROS™.

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 KOLROS™?

It 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).

- KOLROS™ can reduce the 'bad' cholesterol and increase the "good" cholesterol.
- KOLROS™ works by helping to block your body's production of 'bad' cholesterol and 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 be blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. If you correct your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

You need to keep taking KOLROS™, 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 KOLROS™

Do not take KOLROS™

- If you are allergic to rosuvastatin or to 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 KOLROS™ stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking KOLROS™ 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 KOLROS™ 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.

KOLROS™ Warnings and precautions

Talk to your doctor or pharmacist before taking KOLROS™:

- 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.
- If you regularly drink large amounts of alcohol.
- If your thyroid gland is not working properly.
- If you have severe respiratory failure.
- **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. lopinavir/ritonavir, please see Taking other medicines.
- If the patient is under 10 years old: KOLROS™ should not be given to children younger than 10 years.
- If the patient is below 18 years of age: The KOLROS™ 40 mg tablet is 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 KOLROS™ 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 KOLROS™ to suit you.

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

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

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 KOLROS™.

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 KOLROS™

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) 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 or lopinavir/ritonavir (used to fight the HIV infection - please see section Take special care with KOLROS™). The effects of these medicines could be changed by KOLROS™ or they could change the effects of KOLROS™.

KOLROS™ with food and drink

You can take KOLROS™ with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Ask your doctor or pharmacist for advice before taking any medicine. Do not take KOLROS™ if you are pregnant or breast-feeding. If you become pregnant while taking KOLROS™ stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking KOLROS™ by using suitable contraception.

Driving and using machines

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

KOLROS™ contains lactose monohydrate

KOLROS™ 10 mg film-coated tablets contains 60 mg of lactose monohydrate. KOLROS™ 20 mg film-coated tablets contains 120 mg of lactose monohydrate. KOLROS™ 40 mg film-coated tablets contains 240 mg of lactose monohydrate.

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 KOLROS™.

3. How to take KOLROS™

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

Usual doses in adults

If you are taking KOLROS™ for high cholesterol:

Starting dose:

Your treatment with KOLROS™ 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 a breakline.

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 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 KOLROS™ 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 KOLROS™ 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 KOLROS™ 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.

Usual doses in children aged 10-17 years

The usual start dose is 5 mg. Your doctor may increase your dose to find the right amount of KOLROS™ for you. The maximum daily dose of KOLROS™ is 20 mg. Take your dose once a day. KOLROS™ 40 mg tablet should not be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water.

Take KOLROS™ once daily. You can take it at any time of the day.

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 KOLROS™ that is right for you.

If you take more KOLROS™ 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 KOLROS™.

If you forget to take KOLROS™

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 KOLROS™

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

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

4. Possible side effects

Like all medicines, KOLROS™ 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 KOLROS™ 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 KOLROS™ 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*.

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

Common possible side effects (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 KOLROS™ (only KOLROS™ 40 mg).
- Diabetes, mostly in those with blood sugar at the upper end of „normal“.

Uncommon possible side effects (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 KOLROS™ (only KOLROS™ 10 mg and 20 mg).

Rare possible side effects (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 KOLROS™ and seek medical help immediately

- Muscle damage - as a precaution, stop taking KOLROS™ 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
- Joint pain.

Very rare possible side effects (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)
- Memory loss
- Gynecomastia (breast enlargement in men).

Side effects of unknown frequency may include (frequency cannot be estimated from available data):

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

Possible side effects:

- Sleep disturbances, including insomnia and nightmares
- Memory loss
- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever

- 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store KOLROS™

Store below 25° C and protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use KOLROS™ this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

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 KOLROS™ contains

The active substance is rosuvastatin.

10 mg film-coated tablet contains 10 mg, resp. 20 mg, resp. 40 mg of rosuvastatin as rosuvastatin calcium.

The other ingredients are:

Core: Lactose monohydrate, Cellulose, microcrystalline, Croscarmellose sodium, Silica colloidal anhydrous, Magnesium stearate, Coating layer: Hypromellose 2910/5, Macrogol 6000, Titanium dioxide (E171), Talc, Iron oxide red (E172).

What KOLROS™ looks like and contents of the pack

KOLROS™ 10 mg film-coated tablets are light pink, film-coated, oval, biconvex tablets with halving score.

KOLROS™ 20 mg film-coated tablets are pink, film-coated, oval, biconvex tablets.

KOLROS™ 40 mg film-coated tablets are dark pink, film-coated, oval, biconvex tablets.

Pack sizes: 30, film-coated tablets

Manufacturer

Zentiva, k.s., Prague, the Czech Republic
Packed by Benta S.A.L., Dbayah- Lebanon

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