

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 more 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.

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

What is in this leaflet

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

1. What BENEFIT is and what it is used for

BENEFIT belongs to a group of medicines called statins.

You have been prescribed **BENEFIT** because:

You have a high cholesterol level. This means you are at risk from a heart attack or stroke. **BENEFIT** 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 **BENEFIT**.

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 BENEFIT

BENEFIT 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).

BENEFIT 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 **BENEFIT**, 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 BENEFIT

Do not take BENEFIT:

- If you have ever had an allergic reaction to **BENEFIT**, or to any of its ingredients.
- If you are pregnant or breast-feeding.
- If you become pregnant while taking **BENEFIT** stop taking it immediately and tell your doctor.

Women should avoid becoming pregnant while taking **BENEFIT** 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 **BENEFIT** 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 **BENEFIT**.

- 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 infection e.g. ritonavir with lopinavir and/or atazanavir, please see “Other medicines and **BENEFIT**”.
- 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 **BENEFIT** can lead to serious muscle problems (rhabdomyolysis), please see “Other medicines and **BENEFIT**”.
- If you are over 70 (as your doctor needs to choose the right start dose of **BENEFIT** 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 **BENEFIT** to suit you.
- If any of the above applies to you (or if you are not sure):

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

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: **BENEFIT** should not be given to children younger than 6 years. If the patient is below 18 years of age: The **BENEFIT** 40 mg tablet is not suitable for use in children and adolescents below 18 years of age.

Other medicines and BENEFIT

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 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).
- fusidic acid (an antibiotic – please see below and Warnings and precautions), an oral contraceptive (the pill).
- regorafenib (used to treat cancer).
- hormone replacement therapy 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, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.

The effects of these medicines could be changed by **BENEFIT** or they could change the effect of **BENEFIT**.

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

Pregnancy and breast-feeding

Do not take **BENEFIT** if you are pregnant or breast-feeding. If you become pregnant while taking **BENEFIT** stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking **BENEFIT** 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 **BENEFIT** – it will not affect their ability. However, some people feel dizzy during treatment with **BENEFIT**.

If you feel dizzy, consult your doctor before attempting to drive or use machines.

BENEFIT 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 **BENEFIT**.

For a full list of ingredients, please see Contents of the pack and other information.

3. How to take BENEFIT

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 **BENEFIT** for high cholesterol:

Starting dose

Your treatment with **BENEFIT** 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 levels.
- 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 **BENEFIT** 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 **BENEFIT** 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 **BENEFIT** 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 **BENEFIT** 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 **BENEFIT** for you. The maximum daily dose of **BENEFIT** 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. **BENEFIT** 40 mg tablet should not be used by children.

Taking your tablets

Swallow each tablet whole with a drink of water. Take **BENEFIT** 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 **BENEFIT** that is right for you.

If you take more **BENEFIT** 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 **BENEFIT**.

If you forget to take **BENEFIT**

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 **BENEFIT**

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

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 **BENEFIT** 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 **BENEFIT** 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).

Common possible side effects (these may affect between 1 in 10 and 1 in 100 patients):

- 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 **BENEFIT** tablets (only **BENEFIT** 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 possible side effects (these may affect between 1 in 100 and 1 in 1,000 patients):

- 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 **BENEFIT** tablets (only **BENEFIT** 5 mg, 10 mg and 20 mg).

Rare possible side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- 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 **BENEFIT** and seek medical help immediately.
- Muscle damage in adults – as a precaution, stop taking **BENEFIT** 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 possible side effects (these may affect less than 1 in 10,000 patients):

- 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 and breast enlargement in men (gynaecomastia).

Side effects of unknown frequency may include:

- 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 injury and muscle weakness that is constant.

Reporting of side effects:

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store **BENEFIT**

Do not store above 30°C. Store in the original package.

Keep out of the sight and reach of children.

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

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.

6. Contents of the pack and other information

What **BENEFIT** contains

The active substance in **BENEFIT** is rosuvastatin. **BENEFIT** 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, calcium phosphate, crospovidone, copovidone, talc, sodium stearyl fumarate.

BENEFIT 5 mg, 10 mg, 20 mg: Film: AquaPolish yellow, purified water. **BENEFIT** 40 mg: AquaPolish pink, purified water.

Contents of the pack

Box with 30 tablets of 5 mg rosuvastatin in a blister packs.

Box with 30 tablets of 10 mg rosuvastatin in a blister packs.

Box with 30 tablets of 20 mg rosuvastatin in a blister packs.

Box with 30 tablets of 40 mg rosuvastatin in a blister packs.

Marketing Authorisation Holder and Manufacturer

ZADA Pharmaceuticals Ltd.

Donji Bistarac without number

75 300 Lukavac

Bosnia and Herzegovina

Data of first authorization / renewal of the authorisation in Bosnia and Herzegovina:

BENEFIT, film-coated tablets, 30x5 mg tablets:
Number: 04-07.3-1-1812/14 Date: 24.04.2018.

BENEFIT, film-coated tablets, 30x10 mg tablets:
Number: 04-07.3-1-1813/14 Date: 24.04.2018.

BENEFIT, film-coated tablets, 30x20 mg tablets:
Number: 04-07.3-1-1814/14 Date: 24.04.2018.

BENEFIT, film-coated tablets, 30x40 mg tablets:
Number: 04-07.3-1-1815/14 Date: 24.04.2018.