
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZUVAMOR® 5: 5 mg film-coated tablet

ZUVAMOR® 10: 10 mg film-coated tablet

ZUVAMOR® 20: 20 mg film-coated tablet

ZUVAMOR® 40: 40 mg film-coated tablet

Rosuvastatin

Contains sugar: lactose monohydrate

ZUVAMOR 5: Each tablet contains 94,88 mg lactose monohydrate

ZUVAMOR 10: Each tablet contains 91,30 mg lactose monohydrate

ZUVAMOR 20: Each tablet contains 182,60 mg lactose monohydrate

ZUVAMOR 40: Each tablet contains 168,32 mg lactose monohydrate

Read all of this leaflet carefully before you start taking ZUVAMOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZUVAMOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ZUVAMOR is and what it is used for

ZUVAMOR belongs to a group of medicines called HMG-CoA reductase inhibitors (also known as “statins”).

ZUVAMOR is used to lower high levels of blood fats which are called lipids, usually when changes to diet and exercise have failed to do this. ZUVAMOR, in addition to diet, lowers “bad” cholesterol (LDL-C) and increases “good” cholesterol (HDL-C) in the blood.

In adult patients who have an increased risk of cardiovascular disease, ZUVAMOR has been shown to reduce non-fatal heart attacks, non-fatal strokes and procedures such as stents and bypass surgery for heart disease.

2. What you need to know before you take ZUVAMOR

Do not take ZUVAMOR

- if you are hypersensitive (allergic) to rosuvastatin, similar medicines, or to any of the other ingredients of ZUVAMOR.
- If you currently have liver disease.
- If you have severe kidney problems
- If you are taking a medicine called ciclosporin (used for example, after an organ transplant).
- If you have any disease of the muscles.
- If you are pregnant, trying to become pregnant or are breastfeeding.

Warnings and precautions

Take special care with ZUVAMOR:

Before taking ZUVAMOR, tell your doctor, pharmacist or other health care professional:

- If you have high blood sugar or raised HbA1c (a measure of blood sugar).
- If you have ever been told that you have problems with your liver or kidneys.
- If you have any unexplained aches or pains in your muscles or have a history of muscle pain.
- If you regularly drink large amounts of alcohol.
- If you have an underactive thyroid gland.
- If you are taking protease inhibitors (used to fight the HIV infection).
- If you have severe respiratory failure.

Whilst taking your tablets, tell your doctor, pharmacist or other health care professional if you have any unexplained aches or pains in your muscles.

If you become seriously ill or you go into hospital, let the medical staff looking after you know that you are taking ZUVAMOR, as it may be better for you to stop taking it for a short time.

Other medicines and ZUVAMOR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, tell your doctor if you are taking any of the following medicines:

- ciclosporin (used for example, after an organ transplant),
- warfarin or clopidogrel (or any other medicine used for thinning your blood),
- gemfibrozil or fenofibrate (fibric acid medicine used to lower the fat in your blood),
- niacin and nicotinic acid (used for example, to lower the fat in your blood)
- antacids (medicines used to treat heartburn),
- erythromycin (an antibiotic), fusidic acid (an antibiotic – please see below and Warnings and precautions),
- regorafenib (used to treat cancer),
- darolutamide (used to treat cancer),
- 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 ZUVAMOR can lead to serious muscle problems (rhabdomyolysis), please see “Other medicines and ZUVAMOR”.
- If you are taking antiviral medications alone or in combination such as lopinavir, ritonavir, sofosbuvir, velpatasvir, voxilaprevir, grazoprevir, elbasvir, ombitasvir, paritaprevir, dasabuvir, glecaprevir, pibrentasvir - (used to fight infections, including the HIV infection), regorafenib and darolutamide (used to treat cancer).

ZUVAMOR with food and drink

ZUVAMOR may be taken with or without food.

Pregnancy and breastfeeding

Do not take ZUVAMOR if you are pregnant or breastfeeding.

If you become pregnant while taking ZUVAMOR stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking ZUVAMOR by using suitable contraception.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

ZUVAMOR is not expected to affect your ability to drive or to operate machinery. However, some people feel dizzy during treatment with ZUVAMOR. If you feel dizzy, consult your doctor before attempting to drive or use machines.

ZUVAMOR contains lactose

ZUVAMOR 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 ZUVAMOR. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ZUVAMOR.

3. How to take ZUVAMOR

Do not share medicines prescribed for you with any other person.

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

Treatment with ZUVAMOR is usually started with one 5 mg tablet taken once daily. Some people may be asked to start treatment with either a 10 mg or a 20 mg tablet taken once daily.

People of Asian origin should start treatment with one 5 mg tablet taken once a day. The 40 mg dose is contraindicated in these patients.

After checking the amount of fats in your blood, your doctor may decide to increase your dose until you are taking the amount of ZUVAMOR that is right for you. In adults the maximum daily dose is 40 mg. In children 10 years of age and above, the maximum daily dose is 20 mg.

Your doctor will tell you how long your treatment with ZUVAMOR will last. Do not stop taking your tablets even if you are feeling well, unless your doctor tells you to or unless you become pregnant. If you have the impression that the effect of ZUVAMOR is too strong or too weak, tell your doctor or pharmacist.

You can take your tablet at any time of the day, with or without food.

However, try to take your tablet at the same time each day, this will help you to remember to take

Swallow each tablet whole with a drink of water.

If you take more ZUVAMOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ZUVAMOR

Skip the missed dose (tablet) and take your next dose as usual. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ZUVAMOR can have side effects.

Not all side effects reported for ZUVAMOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZUVAMOR, please consult your health care provider for advice.

Some people may develop a severe allergic reaction.

If any of the following happens, stop taking ZUVAMOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you develop difficulty in breathing with or without swelling of the face, lips, tongue and/or throat.
- If you develop swelling of the face, lips, tongue, and/or throat, which may cause difficulty in swallowing.
- If you develop severe itching of the skin (with raised lumps).

If you have any aches or pains in your muscles for which you do not know a reason or which go on for longer than you might expect, you should talk to a doctor as soon as

possible. The doctor may perform a blood test to check the condition of your muscles. Increases in HbA1c, a measure of blood sugar, have been reported in patients taking ZUVAMOR. In some instances, this increase meets the diagnosis of diabetes mellitus, mainly in patients already at high risk for developing this condition.

Liver problems:

Your doctor should do blood tests to check your liver before you start taking ZUVAMOR and if you have symptoms of liver problems while you take ZUVAMOR. Call your doctor right away if you have any of the following symptoms of liver problems:

- feel unusually tired or weak
- loss of appetite
- upper stomach pain
- dark urine
- yellowing of your skin or the whites of your eyes

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- dizziness
- constipation
- nausea (feeling like you want to vomit)
- stomach pain
- muscle pain
- lack of energy

Less frequent side effects:

- Skin rash, itching and hives.
- Muscle disease and muscle ache (rhabdomyolysis), and infection of the pancreas or a severe allergic reaction.
- Jaundice (yellowing of the skin), infection of the liver, joint pain or memory loss.

Additional unwanted effects of unknown frequency that may occur are:

- Depression and sleep disturbances, including difficulty in sleeping and nightmares.
- Breast enlargement in men and women (gynaecomastia).

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- Muscle weakness that is constant and numbness, tingling or pain in the arms or legs (peripheral neuropathy).
 - A decrease in platelets, which are cells that help you stop bleeding if you get a cut (thrombocytopenia).

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> . By reporting side effects, you can help provide more information on the safety of ZUVAMOR

Acino Pharma (Pty) Ltd: E-mail: drugsafety_za@acino.swiss Tel: 060 998 7896

5. How to store ZUVAMOR

Store all medicines out of reach of children.

Store at or below 30 °C.

If your tablet comes in a plastic bottle, keep the lid tightly closed in order to protect from light and moisture.

If your tablet comes in blisters, keep your tablets in the carton until they are required for use.

Do not take your ZUVAMOR after the expiry date on the label or container.

Return all unused tablets to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZUVAMOR contains

The active substance is rosuvastatin. ZUVAMOR tablets have either 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin.

The other ingredients are calcium phosphate, crospovidone, glycerol triacetate, hypromellose, iron oxide red (E172), iron oxide yellow (E172), lactose monohydrate, magnesium stearate, microcrystalline cellulose and titanium dioxide (E171).

What ZUVAMOR looks like and contents of the pack

Four tablet strengths are available:

ZUVAMOR 5: Yellow, film coated, round, biconvex, approximately 7 mm (diameter)

intagliated tablet; obverse side "ZD4522 5", reverse side none.

ZUVAMOR 10: Pink, film coated, round, biconvex, approximately 7 mm (diameter)

intagliated tablet; obverse side "ZD4522 10", reverse side none.

ZUVAMOR 20: Pink, film coated, round, biconvex, approximately 9,1 mm (diameter)

intagliated tablet; obverse side "ZD4522 20", reverse side none.

ZUVAMOR 40: Pink, film coated, oval, biconvex, approximately 11,5 x 7,1 mm (length x width) intagliated tablet; obverse side "ZD4522", reverse side "40".

ZUVAMOR 5-10-20-40 mg tablets are packed in blister packs containing multiples of 7, 10 or 14 tablets

ZUVAMOR 5-10-20-40 mg tablets are packed either in plastic bottles containing 30, 90, or 100 tablets or in blister packs containing multiples of 7, 10 or 14 tablets.

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd.

106, 16th Road

Midrand, 1686

This leaflet was last revised in

Date on registration certificate:

27 July 2017.

Date of the most recently revised approved patient information leaflet:

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ZUVAMOR 5: 43/7.5/1138

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ZUVAMOR 40: 36/7.5/0355

Access to the corresponding Professional Information