APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ROLTESIM 40 Film-coated tablets

ROLTESIM 80 Film-coated tablets

Simvastatin

Contains sugar: lactose monohydrate 270,80 mg/541,60 mg

Read all of this leaflet carefully before you start taking ROLTESIM

- 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.
- ROLTESIM 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 ROLTESIM is and what it is used for

ROLTESIM belongs to a group of medicines called HMG-CoA reductase inhibitors.

It works by blocking an enzyme that is needed by the body to make cholesterol. Thus, less cholesterol is made.

ROLTESIM is used to reduce the elevated total cholesterol and LDL-cholesterol levels where diet and other forms of therapy do not work.

ROLTESIM is also used in patients with coronary heart disease and elevated cholesterol where diet does not work, to reduce the risk of atherosclerosis

2. What you need to know before you take ROLTESIM

Do not take ROLTESIM:

- If you are hypersensitive (allergic) to simvastatin or any of the other ingredients of ROLTESIM (listed in section 6).
- If you are pregnant or breastfeeding.
- If you have acute or chronic liver problems or disease.
- If you are a female of child-bearing potential.
- If you have Porphyria.
- If you are taking the following medicines that will increase the amount of simvastatin in your blood and in turn increase the risk of muscle side effects:
    - Ketoconazole, itraconazole and posaconazole which are used to treat fungal infections
    - HIV protease inhibitors used to treat HIV infection
    - erythromycin, clarithromycin and telithromycin antibiotics used to treat infections
    - nefazodone used to treat depression
    - gemfibrozil used to treat high cholesterol levels
    - ciclosporin used to suppress the immune system
    - danazol

Warnings and precautions

Tell your doctor if you have any of the following as you may then require a lower dose, special monitoring or stopping of ROLTESIM:

- if you develop unexplained muscle pain, tenderness or weakness. On rare occasions muscle problems can be serious including muscle breakdown resulting in kidney damage. Your doctor will do a blood test to check for certain muscle problems.
- You might be more at risk to develop muscle problems if you are over 65 years, of female gender, have uncontrolled underactive thyroid problems or have kidney problems.
- If you drink substantial amounts of alcohol and/or have a history of liver disease.
- If you are taking the following in addition to ROLTESIM, please tell your doctor or pharmacist. In certain cases, your doctor may want to change the dose, stop ROLTESIM or other precautions may be necessary:
    - Anticoagulants may increase bleeding.
    - Ciclosporin, fibric acid derivatives and niacin may increase the risk of developing muscle problems and kidney failure.
    - Digoxin may increase the digoxin blood levels increasing the risk of side effects.
    - Cholestyramine which may make less ROLTESIM available for the body to use.

Children and adolescents

It is not recommended for children as the safety and efficacy has not been established.

Other medicines and ROLTESIM

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

See section "**2. What you need to know before you take ROLTESIM."**

ROLTESIM with drink

Avoid large quantities of grapefruit juice (> 1 ℓ daily). Grapefruit juice can prevent the body from breaking down ROLTESIM and therefore increase the risk of the muscle side effects of unexplained muscle pain, tenderness or weakness.

Pregnancy and breastfeeding and fertility

Do not take ROLTESIM if you are pregnant or breast feeding.

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

ROLTESIM may cause dizziness or vertigo. Therefore, do not drive or operate machinery.

It is not always possible to predict to what extent ROLTESIM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ROLTESIM affects them.

ROLTESIM contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ROLTESIM.

3. How to take ROLTESIM

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

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

- You must follow a cholesterol-lowering diet and continue with the diet during treatment.
- The tablet should be swallowed whole.
- ROLTESIM can be taken with meals or on an empty stomach.
- For high cholesterol: The initial starting dose is 10 mg a day to be taken as a single dose in the evening. Your doctor may increase your dose to a maximum of 80 mg a day to be taken as a single dose in the evening or reduce your dose depending on your cholesterol level.
- For coronary heart disease: The starting dose is 20 mg a day to be taken as a single dose in the evening. Your doctor will adjust your dose if necessary.
- If you are taking ROLTESIM together with cholestyramine, take ROLTESIM 1 hour before or 4 hours after taking cholestyramine.

Your doctor will tell you how long your treatment with ROLTESIM will last. If you have the impression that the effect of ROLTESIM is too strong or too weak, tell your doctor or pharmacist.

If you take more ROLTESIM than you should

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

In the event of overdosage (if you take too many tablets) or is someone else has taken your medicine by mistake, you, or this other person, will require general supportive measures.

Contact your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take ROLTESIM

Take ROLTESIM as prescribed. If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten individual dose.

4. Possible side effects

ROLTESIM can have side effects.

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

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

- Hypersensitivity reactions which include an allergic skin disorder, sudden difficulty in breathing, speaking and swallowing, swelling of the lips, tongue, face and neck.
- Yellowing of the eyes and skin, called jaundice.

These are all very serious side effects. If you have them, you may have had a serious reaction to ROLTESIM. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Upper respiratory tract infection, urinary tract infection
- Changes in the way your heart beats for example, if you notice it beating faster
- Difficulty breathing

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Anaemia – tiredness, looking pale
- Diabetes mellitus
- Headache and inability to sleep
- Dizziness
- Bronchitis, sinusitis (infections of upper chest and nose)
- Constipation, diarrhoea, nausea, vomiting, flatulence, heartburn
- Stomach pain and cramps
- Inflammation of stomach (gastritis) and pancreas (pancreatitis)
- Skin rash, hair loss, eczema.
- Muscle pain, muscle cramps
- Oedema/swelling

Less frequent

- Arthritis, pain in joints, photosensitivity, fever, flushing, malaise (general sense of being unwell, often accompanied by fatigue, pain or lack of interest in activities)
- Weight gain

- Depression
- Dizziness, fatigue, lack of strength, tingling, weakness or numbness feeling in hands, arms, leg or feet
- Memory loss, forgetfulness, amnesia, memory impairment, confusion
- Itching, skin changes (discoloration, dryness of skin/mucous membranes, changes to hair or nails
- Muscle weakness, muscle pain.
- Erectile dysfunction

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or 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 ROLTESIM.

The applicant can be reached at the following contact number: 010 045 2500.

5. How to store ROLTESIM

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from light.
- Keep the blister strips in the outer carton until required for use.
- Do not use after the expiry date stated on the packaging material.
- Return all unused medicine 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 ROLTESIM contains

- The active substance is simvastatin.
- ROLTESIM 40/80 contains 40 mg and 80 mg of simvastatin respectively.
- The other ingredients are ascorbic acid, butylated hydroxy anisole, citric acid monohydrate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, Opadry Pink 20A54535. The Opadry contains hydroxypropyl cellulose, hypromellose, iron oxide red, talc, titanium dioxide

What ROLTESIM looks like and contents of the pack

ROLTESIM 40: Pink-coloured, oval, biconvex, intact, film-coated tablets embossed with ‘SVN 40’ on one side and plain on the other side.

ROLTESIM 80: Pink-coloured, capsule-shaped, biconvex, intact, film-coated tablets embossed with ‘SVN 80’ on one side and scored on the other side.

Opaque PVC and aluminium foil blister strips of 10 tablets, packed in 30’s.

Blister pack comprises of non-toxic, white opaque, PVC/PVDC film with backing of plain blister foil. with VMCH coating.

Suitable number of blister strips packed in an outer cardboard carton.

Blister strips of 10’s is packed into unit cartons for pack sizes of 30’s.

Holder of Certificate of Registration

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ROLTESIM 40: A38/7.5/0372

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Access to the corresponding Professional Information

To be provided