

PATIENT INFORMATION LEAFLET FOR SIMVOTIN 10 , 20 & 40

SCHEDULING STATUS: **S4**

SIMVOTIN 10 Tablets

SIMVOTIN 20 Tablets

SIMVOTIN 40 Tablets

Simvastatin

Contains sugar

SIMVOTIN 10 Tablets contains 72,210 mg

SIMVOTIN 20 Tablets contains 144,420 mg

SIMVOTIN 40 Tablets contains 288,840 mg

Read all of this leaflet carefully before you start taking **SIMVOTIN** Tablets

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- **SIMVOTIN** Tablets have 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 **SIMVOTIN** Tablet is and what it is used for
2. What you need to know before you take **SIMVOTIN** Tablet
3. How to take **SIMVOTIN** Tablet
4. Possible side effects
5. How to store **SIMVOTIN** Tablet
6. Contents of the pack and other information

1. What **SIMVOTIN** Tablet is and what it is used for

SIMVOTIN Tablets are used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and

fatty substances called triglycerides in the blood. In addition, **SIMVOTIN** Tablets raise levels of “good”

cholesterol (HDL cholesterol).

You should stay on a cholesterol-lowering diet while taking **SIMVOTIN** Tablets. **[PRODUCT NAME]**

Tablets belongs to the class of medicines called statins.

SIMVOTIN Tablets **are used along** with diet, if you have:

- a raised cholesterol level in your blood (primaty hypercholesterolaemia) or elevated fat levels in your blood (mixed hyperlipidaemia)

- a hereditary illness (heterozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood.
- Heart disease and high cholesterol and not responding to change in diet to:
 - reduce the risk of death
 - reduce the risk of heart attack
 - reduce the risk of receiving surgery such as a bypass
- slow the progression of heart disease

2. What you need to know before you take SIMVOTIN Tablets

Do not take SIMVOTIN Tablets:

- if you are hypersensitive (allergic) to simvastatin or other statin or any of the other ingredients of **SIMVOTIN** Tablets (listed in section 6).
- if you current have liver problems
- if you have a disorder called porphyria
- if you are pregnant or breastfeeding
- Unexplained raised levels of liver enzymes
- if you are taking medicine (s) with one or more than one of the following active ingredients:
 - Itraconazole, ketoconazole, posaconazole or voriconazole (used to treat fungal infections)
 - erythromycin, clarithromycin or telithromycin (antibiotics for infections)
 - HIV protease inhibitors such as ritonavir, saquinavir, nelfinavir (HIV protease inhibitors are used for HIV infections)

- boceprevir and telaprevir (medicines used to treat hepatitis C)
- nefazodone (a medicine for depression)
- medicines containing cobicistat
- gemfibrozil (a medicine for lowering cholesterol)
- ciclosporin (a medicine often used in organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis: a female health disorder that occurs when cells from the lining of the womb (uterus) grow in other areas of the body.

Safety of **SIMVOTIN** Tablets in porphyria (a group of rare blood pigment disorders) has not been established.

Warnings and precautions

Take special care with **SIMVOTIN** Tablets:

- if you drink large amounts of alcohol
- if you have ever had liver disease. **SIMVOTIN** Tablets may not be right for you.
- if you develop kidney failure resulting from muscle breakdown (rhabdomyolysis).

Other factors

which can lead to kidney failure include severe infection, low blood pressure, severe problems with

your metabolism (a process by which your body uses to get or make energy from the food you eat),

problems with your hormonal system, imbalance of electrolyte (such as potassium, sodium),

uncontrolled fits, operation or injury.

- if you are due to have an operation. You may need to stop taking **SIMVOTIN** Tablets for a short time.
- if you are due to have an operation. You may need to stop taking **SIMVOTIN** Tablets for a short time.
- Your doctor should do a blood test before you start taking **SIMVOTIN** Tablets. This is to check how well your liver is working.
- Your doctor may also want you to have blood tests to check how well your liver is working after you start taking **SIMVOTIN** Tablets.
- While you are taking **SIMVOTIN** Tablets 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.
- if you have severe lung disease.
- if you are Asian, because a different dose may be applicable to you.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or

weakness. This is because on rare occasions, muscle problems can be serious, including muscle

breakdown resulting in kidney damage and, rarely, death.

You should stop SIMVOTIN Tablets immediately, if you have been diagnosed muscle problems

(myopathy) or suspect that you have myopathy.

The risk of muscle breakdown is greater at higher doses of **SIMVOTIN** Tablets, particularly the 80 mg

dose. The risk of muscle breakdown is also greater in certain patients. Talk with your doctor if any of the

following applies:

- if you are older than 65 years
- if you are a female
- if you have kidney problems
- If you have uncontrolled low levels thyroid (hypothyroidism)
- if you have a personal or family history of muscle disorders,
- if you previously experienced muscle disorders with statin or fibrate use,
- if you consume large amounts of alcohol

Children and adolescents

SIMVOTIN Tablets should not be given to children, since the safety and effectiveness of **SIMVOTIN**

Tablets have not been determined in children.

Other medicines and SIMVOTIN Tablets

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). It is particularly important to tell your doctor if you are

taking any of the following medicines. Taking **SIMVOTIN** Tablets with any of these medicines can increase

the risk of muscle problems (some of these have already been listed in the above section

“Do not take

SIMVOTIN Tablets”).

- ciclosporin (a medicines used inn organ transplant patients)
- danazol (a man-made hormone used to treat endometriosis, a condition in which the lining of the uterus grows outside the uterus)
- medicines with the active ingredient like itraconazole, ketoconazole, fluconazole, voriconazole or posaconazole (medicines for fungal infections)
- fibrates like gemfibrozil (medicines for lowering cholesterol)
- erythromycin, clarithromycin, telithromycin or fusidic acid (medicines for bacterial infections)
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir, and saquinavir (medicines for AIDS)
- nefazodone (a medicine for depression)
- boceprevir, telaprevir, elbasvir, grazoprevir (medicine used to treat hepatitis C)
- amiodarone (used to treat an irregular heartbeat)
- verapamil, diltiazem, or amlodipine (used to treat high blood pressure, chest pain associated with

heart disease, or other heart conditions)

- colchicine (used to treat gout).
- medicines with the active ingredient cobicicstat (used to treat HIV infection),
- lomitapide (used to treat a serious and rare genetic cholesterol condition),
- daptomycin (a medicine used to treat complicated skin and skin structure infections and

bacteraemia). It is possible that side effects affecting the muscles may be higher when this

medicine is taken during treatment with simvastatin (e.g. **SIMVOTIN**). Your doctor may decide that

you stop taking **SIMVOTIN** for a while.

- ticagrelor (antiplatelet medicine)

Also, tell your doctor or pharmacist if you are taking or have recently taken any of the following:

- Medicines to prevent blood clots, such as warfarin (anticoagulants)
- cholestyramine (another medicine for lowering cholesterol)
- niacin (another medicine for lowering cholesterol)
- digoxin (a medicine used to treat heart problems)
- rifampicin (medicine used to treat tuberculosis)

Also tell your doctor if you are taking niacin (nicotinic acid) or a niacin-containing product and are Chinese.

You should also tell any doctor who is prescribing a new medicine for you that you are taking

SIMVOTIN

Tablets.

SIMVOTIN Tablets with food, drink and alcohol

Grapefruit juice contains one or more components that alter how the body uses some medicines,
including **SIMVOTIN** Tablets. Consuming grapefruit juice should be avoided.

Pregnancy, breastfeeding and fertility

You should not take **SIMVOTIN** Tablets if you are pregnant or breastfeeding your baby.

Do not take **SIMVOTIN** Tablets if you are pregnant, trying to get pregnant or think you may be pregnant. If

you get pregnant while taking **SIMVOTIN** Tablets, stop taking it immediately and contact your doctor. Do

not take **SIMVOTIN** Tablets if you are breastfeeding, because it is not known if the medicine is passed into breast milk.

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

SIMVOTIN Tablets may cause dizziness.

You should not drive or use machinery until you know what the effect of **SIMVOTIN** Tablets will be on you.

If you feel dizzy during treatment with **SIMVOTIN** Tablets, consult your doctor before attempting to drive or use machines.

SIMVOTIN Tablets contains Lactose monohydrate

SIMVOTIN Tablets contain lactose monohydrate. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **SIMVOTIN** Tablets.

3. How to take SIMVOTIN Tablets

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

Always take **SIMVOTIN** Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual starting dose of **SIMVOTIN** Tablets is 10 mg to 20 mg taken once daily every evening. Your doctor may increase or decrease your daily dose at intervals of at least 4 weeks. The maximum recommended daily dose is 80 mg.

Your doctor will determine the appropriate tablet strength for you, depending on your condition.

Your doctor will tell you how long your treatment with **SIMVOTIN** Tablets will last.

If you have the impression that the effects of **SIMVOTIN** Tablets is too strong or too weak,
tell your doctor

or pharmacist.

If you take more SIMVOTIN Tablets than you should

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

hospital or poison centre. Take the **SIMVOTIN** Tablets pack with you.

If you forget to take SIMVOTIN Tablets

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking using SIMVOTIN

- Your levels of cholesterol may rise again.

If you have any further questions on the use of **SIMVOTIN** Tablets, ask your doctor or pharmacist.

4. Possible side effects

SIMVOTIN Tablets can have side effects.

Not all side effects reported for **SIMVOTIN** Tablets are included in this leaflet. Should your general health

worsen or if you experience any untoward effects while taking **SIMVOTIN** Tablets, please consult your

health care provider for advice.

If any of the following happens, stop taking **SIMVOTIN** Tablets and tell your doctor immediately or go to

the casualty department at your nearest hospital:

- hypersensitivity (allergic) reactions including:
 - swelling of the face, tongue and throat which may cause difficulty in breathing,
 - severe muscle pain usually in the shoulders and hips,
 - rash with weakness of limbs and neck muscles,
 - pain or inflammation of the joints,
 - inflammation of the blood vessels,
 - unusual bruising, hives, skin sensitivity to the sun, fever, flushing,
 - shortness of breath and feeling unwell,
 - lupus-like disease picture (including rash, joint disorders, and effects on blood cells).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to

SIMVOTIN Tablets. 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:

- changes in the way your heart beats, for example, if you notice it beating irregular and often very fast,
- muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage,
- numbness or weakness of the arms and legs (peripheral neuropathy),
- inflammation of the pancreas, often with severe upper stomach pain, nausea and vomiting (pancreatitis),
- inflammation of the liver with the following symptoms: yellowing of the skin and eyes, itching, dark-coloured urine or pale-coloured stool, feeling tired or weak, loss of appetite, liver failure.

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

Tell your doctor if you notice any of the following:

Uncommon/Less frequent side effects:

-
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (low number of red blood cells), frequent infections such as fever, severe chills, sore throat or mouth (low number of white blood cells),
 - headache, dizziness, tiredness, pins and needles (paraesthesia),
 - constipation, diarrhoea, feeling sick (nausea), being sick (vomiting), wind, indigestion, stomach pain,
 - skin rash, loss of hair (alopecia) muscle pain, muscle cramps, muscle inflammation, unusual weakness,
 - trouble sleeping,
 - sleep disturbances, including nightmares,
 - poor memory, memory loss, confusion,
 - diabetes.

Side effects with unknown frequency

- weight gain,
- sexual dysfunction,
- inflammation of the lungs causing breathing problems including persistent cough and/or shortness of breath or fever,
- tendon problems, sometimes complicated by rupture of the tendon.
- depression

Effect on Laboratory tests

- low level blood cells (red, white and platelets),
- increased creatine kinase (from muscle) in blood,
- presence of myoglobin in urine (marker for muscle breakdown),
- increase in blood transaminase, alkaline phosphatase, gamma glutamyl transpeptidase (liver function enzymes),
- increase in blood glucose.

If you notice any side effects not mentioned in this leaflet, please tell 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 **SIMVOTIN** Tablets.

5. How to store SIMVOTIN Tablets

- Store at or below 25 °C, protected from light and moisture.
- Do not remove the blister from the carton until required for use.
- Keep out of the reach and sight of children.
- Do not take **SIMVOTIN** Tablets after the expiry date stated on the pack. The expiry date refers to
the last day of that month.
- 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 SIMVOTIN Tablets contains:

- The active substance is simvastatin
- The other ingredients are
 - Lactose monohydrate
 - Pregelatinised starch
 - Ascorbic acid
 - Citric acid monohydrate
 - Cellulose microcrystalline (PH 101)
 - Water purified
 - Butylated hydroxyl anisole (BHA)
 - Isopropyl alcohol
 - Croscarmellose sodium,
 - Magnesium stearate
 - Hydroxypropyl cellulose
 - Hypromellose 15Cp

- Titanium dioxide (C.L No.77891)
- Talc
- Iron oxide red (C.L No. 77491)
- Iron oxide black (C.L No. 77499)
- Iron oxide yellow (C.L No. 77492)

What SIMVOTIN Tablets looks like and contents of the pack

SIMVOTIN 10 Tablets: Peach coloured, film-coated, oval shaped tablets debossed with 'SST' on one side

and '10' on other side with intact coating.

SIMVOTIN 20 Tablets: Tan coloured, film- coated, oval shaped tablets debossed with 'SST' on one side

and '20' on other side with intact coating.

SIMVOTIN 40 Tablets: Brick red coloured, film-coated, oval shaped tablets debossed with 'SST' on one

side and '40' on other side with intact coating.

28, 30 or 100 tablets packed in PVC/PVdC blister strips.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICAL (PTY) LTD

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South Africa

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SIMVOTIN 10 Tablets: **36/7.5/0373**

SIMVOTIN 20 Tablets: **36/7.5/0374**

SIMVOTIN 40 Tablets: **36/7.5/0375**

Namibia: NS2 Reg.No.:
Simvotin 10 Tablets: 05/7.5/0218
Simvotin 20 Tablets: 05/7.5/0219
Simvotin 40 Tablets: 05/7.5/0220