PATIENT INFORMATION LEAFLET FOR

CIPLA SIMVASTATIN 10 / 20 / 40 / 80 TABLETS

SCHEDULING STATUS: S4

CIPLA SIMVASTATIN 10, simvastatin 10 mg, film-coated tablets.

CIPLA SIMVASTATIN 20, simvastatin 20 mg, film-coated tablets.

CIPLA SIMVASTATIN 40, simvastatin 40 mg, film-coated tablets.

CIPLA SIMVASTATIN 80, simvastatin 80 mg, film-coated tablets.

Simvastatin

Contains sugar

CIPLA SIMVASTATIN 10: Each film-coated tablet contains 67,70 mg lactose monohydrate.

CIPLA SIMVASTATIN 20: Each film-coated tablet contains 135,40 mg lactose monohydrate.

CIPLA SIMVASTATIN 40: Each film-coated tablet contains 270,80 mg lactose monohydrate.

CIPLA SIMVASTATIN 80: Each film-coated tablet contains 541,60 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking CIPLA SIMVASTATIN

- 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.

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

1. What CIPLA SIMVASTATIN is and what it is used for

CIPLA SIMVASTATIN belongs to a class of medicines that lowers blood cholesterol levels.

CIPLA SIMVASTATIN is indicated in combination with a cholesterol-lowering diet to reduce elevated blood cholesterol levels, where diet and other forms of therapy have not been successful.

CIPLA SIMVASTATIN is also used in patients with calcification (atherosclerosis) of their coronary arteries (blood vessels that supply blood to the heart muscle) and high blood cholesterol levels unresponsive to dietary measures to:

- Reduce the risk of a heart attack.
- Reduce the risk of undergoing a coronary bypass procedure or getting a stent to keep the coronary arteries open.
- Slow the progression of calcification of the coronary arteries.

2. What you need to know before you take CIPLA SIMVASTATIN

Do not take CIPLA SIMVASTATIN

- If you ~~A~~are hypersensitive or allergic to simvastatin, other statins (HMG-CoA reductase inhibitors) or any of the other ingredients ~~in~~ of CIPLA SIMVASTATIN. (listed in **section 6**).
- If you have liver disease.
- If you have abnormal liver function test results. Please discuss this with your doctor if you are unsure.
- If you are pregnant or breastfeeding, since the use of CIPLA SIMVASTATIN may harm your baby (see **"Pregnancy and breastfeeding"**).
- If you have been diagnosed with porphyria.
- If you are taking one or more of the following medicines at the same time:
    - itraconazole, ketoconazole or posaconazole (medicines for fungal infections),
    - medicines for the treatment of Human Immunodeficiency Virus (HIV) infection called protease inhibitors,
    - erythromycin, clarithromycin, or telithromycin (antibiotics),
    - nefazodone (medicine for depression),
    - gemfibrozil (a medicine for lowering high cholesterol),
    - ciclosporin (a medicine often used in organ transplant patients) to suppress your immune system,
    - gemfibrozil (a medicine for lowering cholesterol),
    - danazol (a man-made hormone used to treat for endometriosis: a female health disorder that occurs when cells from the lining of the womb (uterus) grow in other areas of the body,

- lomitapide (used to lower inherited cholesterol) with more than 40 mg of CIPLA SIMVASTATIN.

Warnings and precautions

CIPLA SIMVASTATIN may cause muscle injury, which in turn may result in kidney failure and death. Risk factors for muscle injury include advanced age (> 65 years), female gender, underactive thyroid gland and existing kidney disease. Patients with diabetes mellitus and secondary kidney disease also have an increased risk of developing muscle injury with CIPLA SIMVASTATIN. The risk of muscle injury is furthermore dependent on the dose of CIPLA SIMVASTATIN and is greatest with CIPLA SIMVASTATIN 80. If you experience any muscle pain, tenderness or weakness, immediately stop taking CIPLA SIMVASTATIN and report to your doctor promptly. Muscle symptoms in most cases will resolve with discontinuation of treatment. You may have to go for periodic blood tests to monitor for muscle injury.

Take special care with CIPLA SIMVASTATIN:

- If you develop low blood pressure, are scheduled to undergo surgery, suffer trauma or suffer from epilepsy, please inform your doctor that you are taking CIPLA SIMVASTATIN. It may be necessary to temporarily suspend treatment with CIPLA SIMVASTATIN.
- You may have to go for blood tests to monitor your liver function before you start treatment with CIPLA SIMVASTATIN as well as periodically while you are on treatment. Your doctor will decide when and how often you should go for blood tests. If you develop yellow discolouration of the skin or whites of the eyes, experience pain over the liver area with nausea and vomiting, please inform your doctor immediately.
- CIPLA SIMVASTATIN may increase your blood glucose levels. Please inform your doctor if you experience increased thirst, increased hunger and increased frequency of urination.
- Inform your doctor if you have been diagnosed with kidney disease.

- If you consume large quantities of alcohol, please discuss the use of CIPLA SIMVASTATIN with your doctor. You will require careful monitoring.

Children and adolescents

CIPLA SIMVASTATIN should not be given to children, since the safety and effectiveness of CIPLA SIMVASTATIN have not been established in children

Other medicines and CIPLA SIMVASTATIN

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

In particular, if you are taking any of the following medicines or substances, please discuss this with your treating doctor or pharmacist, as you may require dosage adjustments or other precautions:

- Itraconazole, ketoconazole or posaconazole for fungal infections; medicines for the treatment of Human Immunodeficiency Virus (HIV) infection called protease inhibitors; erythromycin, clarithromycin, or telithromycin (antibiotics); or nefazodone for depression (see **"Do NOT take CIPLA SIMVASTATIN if you"**).
- Gemfibrozil for high cholesterol levels, ciclosporin to suppress your immune system or danazol for endometriosis (see **"Do NOT take CIPLA SIMVASTATIN if you"**).
- Large quantities of grapefruit juice or alcohol (see **"Take special care with CIPLA SIMVASTATIN"** and **"Taking CIPLA SIMVASTATIN with food and drink"**).
- Voriconazole for fungal infections.
- Other medicines to reduce high blood cholesterol levels, such as fibrates or niacin (nicotinic acid).

- Verapamil or diltiazem for angina (chest pain on exertion) or high blood pressure.
- Amiodarone or amlodipine for high blood pressure or heart rhythm disorders.
- Colchicine for gout.
- Digoxin for heart failure or abnormal heart rhythms.
- Blood thinning medicines, such as warfarin.

CIPLA SIMVASTATIN with food, drink and alcohol

CIPLA SIMVASTATIN can be taken with meals or on an empty stomach. CIPLA SIMVASTATIN should be taken in the evening. Avoid taking large quantities of alcohol or grapefruit juice while on CIPLA SIMVASTATIN therapy.

You need to continue with your cholesterol-lowering diet while taking CIPLA SIMVASTATIN.

Pregnancy, breastfeeding and fertility

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 CIPLA SIMVASTATIN.

The active metabolite of CIPLA SIMVASTATIN has been shown to cause abnormalities or death in the foetuses of rats. If you are premenopausal and able to have children, you should not use CIPLA SIMVASTATIN without ensuring that you take adequate contraceptive measures. Please discuss this with your doctor or pharmacist.

Driving and using machines

CIPLA SIMVASTATIN may cause dizziness. If you experience dizziness, you should refrain from driving a car or operating machinery.

It is not always possible to predict to what extent CIPLA SIMVASTATIN 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 CIPLA SIMVASTATIN affects them.

CIPLA SIMVASTATIN contains lactose

CIPLA SIMVASTATIN contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take CIPLA SIMVASTATIN

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

Always take CIPLA SIMVASTATIN exactly as your doctor or pharmacist has told ~~instructed~~ you. You should check with your doctor or pharmacist if you are not sure.

The usual starting dose is 10 mg as a single dose in the evening. Your doctor will decide when to increase your dose and with how much. The usual maximum dose is 80 mg per day.

Your doctor will tell you how long your treatment with CIPLA SIMVASTATIN will last.

If you have the impression that the effect of CIPLA SIMVASTATIN is too strong or too weak, tell your doctor or pharmacist.

You must continue with your cholesterol-lowering diet while you take CIPLA SIMVASTATIN. Swallow the tablets whole.

You can take CIPLA SIMVASTATIN with or without meals.

Children

The safety of CIPLA SIMVASTATIN in children has not been established.

If you take more CIPLA SIMVASTATIN 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 CIPLA SIMVASTATIN

Take CIPLA SIMVASTATIN as prescribed. If you miss a dose of CIPLA SIMVASTATIN, take it as you remember. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule of one tablet in the evening. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

CIPLA SIMVASTATIN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- palpitations or fainting spells
- 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 reaction to CIPLA SIMVASTATIN. 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:

- Those that occur frequently:

- Feeling sick (nausea), being sick (vomiting), wind, indigestion, stomach pain,
- myalgia (soreness and achiness in the muscles that can range from mild to severe),
- Vertigo (a feeling of motion when one is standing/sitting still).
- muscle cramps.

- Those that occur less frequently:
  - Coughing, sneezing, runny nose or sore throat, pain over the sinuses,
  - 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),
  - diabetes,
  - trouble sleeping,
  - headache, dizziness, tiredness, pins and needles (paraesthesia),
  - poor memory, memory loss, confusion,
  - sensitivity to light, eye problem,
  - shortness of breath, hypersensitivity pneumonitis (inflamed lungs),
  - constipation, diarrhoea,
  - skin rash, itching, loss of hair (alopecia), urticaria (hives),
  - lichenoid drug eruptions (rare skin rashes that can be caused by allergen such as medicines, inhaled particles),
  - Muscle pain or weakness, muscle cramps, muscle inflammation, muscle rupture,
  - breast enlargement in men (gynaecomastia).

- Those that occur with unknown frequency:
  - Weight loss,

- depression,
- sleep disturbances, including nightmares,
- weakness and rapid fatigue of muscles under voluntary control (myasthenia gravis). The symptoms might only be limited to eye muscles (ocular myasthenia),
- interstitial lung disease,
- respiratory infections, bronchitis, sinusitis,
- erectile dysfunction,
- sexual 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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA **website**, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By re**porting** side effects, you can help provide more information on the safety of CIPLA SIMVASTATIN.

5. How to store CIPLA SIMVASTATIN

Store in a dry place at or below 25 ºC. Protect from light.

Keep the blisters in the outer carton until required for use.

Store all medicines out of reach of children.

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, for example, toilets.

6. Contents of the pack and other information

What CIPLA SIMVASTATIN contains

The active substance in CIPLA SIMVASTATIN is simvastatin.

CIPLA SIMVASTATIN 10: Each film-coated tablet contains simvastatin 10 mg.

CIPLA SIMVASTATIN 20: Each film-coated tablet contains simvastatin 20 mg.

CIPLA SIMVASTATIN 40: Each film-coated tablet contains simvastatin 40 mg.

CIPLA SIMVASTATIN 80**:** Each film-coated tablet contains simvastatin 80 mg.

The other ingredients in CIPLA SIMVASTATIN are:

Ascorbic acid; butylated hydroxyanisole; citric acid monohydrate, hydroxypropyl cellulose Hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc, titanium dioxide.

What CIPLA SIMVASTATIN looks like and contents of the pack

CIPLA SIMVASTATIN 10: Light pink-coloured, oval, biconvex, intact, film-coated tablets debossed with ‘SVN 10’ on one side and plain on the other side.

CIPLA SIMVASTATIN 20: Tan-coloured, oval, biconvex, intact, film-coated tablets debossed with ‘SVN 20’ on one side and plain on the other side.

CIPLA SIMVASTATIN 40: Pink-coloured, oval, biconvex, intact, film-coated tablets debossed with ‘SVN 40’ on one side and scored on the other side.

CIPLA SIMVASTATIN 80: Pink-coloured, capsule-shaped, biconvex, intact, film-coated tablets debossed with ‘SVN 80’ on one side and break line on the other side.

CIPLA SIMVASTATIN is packed in white opaque PVC/PVDC and aluminium foil blister strips of 10 tablets, packed in 30's.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Namibia: NS2 06/7.5/0295

CIPLA SIMVASTATIN 80: A38/7.5/0371.

Namibia: NS2 06/7.5/0296

Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.