Patient Information Leaflet Information for the

Patient about

CIPLA-SIMVASTATIN 10 / 20 / 40 / 80 TABLETS

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 or your pharmacist.**
- **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.**

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

CIPLA-SIMVASTATIN 10 (Tablets)

CIPLA-SIMVASTATIN 20 (Tablets)

CIPLA-SIMVASTATIN 40 (Tablets)

CIPLA-SIMVASTATIN 80 (Tablets)

WHAT CIPLA-SIMVASTATIN CONTAINS:

The active substance in **CIPLA-SIMVASTATIN** is simvastatin.

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

ascorbic acid, butylated hydroxy-anisole, citric acid monohydrate, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, talc, and titanium dioxide.

CIPLA-SIMVASTATIN 20: Each film-coated tablet contains 20 mg simvastatin. Inactive ingredients include ascorbic acid, butylated hydroxy-anisole, citric acid monohydrate, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, talc, and titanium dioxide.

CIPLA-SIMVASTATIN 40: Each film-coated tablet contains 40 mg simvastatin. Inactive ingredients include ascorbic acid, butylated hydroxyl-anisole, citric acid monohydrate, hydroxypropyl cellulose, hypromellose, iron oxide red, lactose monohydrate, magnesium stearate,

	microcrystalline cellulose, pregelatinised starch, talc, and titanium dioxide.
CIPLA-SIMVASTATIN 80:	Each film-coated tablet contains 80 mg simvastatin. Inactive ingredients include ascorbic acid, butylated hydroxyl-anisole, citric acid monohydrate, hydroxypropyl cellulose, hypromellose, iron oxide red, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, talc, and titanium dioxide.

Contains lactose.

Sugar-free.

WHAT CIPLA-SIMVASTATIN IS USED FOR:

CIPLA-SIMVASTATIN belongs to a class of medicines that lowers blood cholesterol levels. **CIPLA-SIMVASTATIN** is used 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.

BEFORE YOU TAKE CIPLA-SIMVASTATIN:

Do NOT take CIPLA-SIMVASTATIN if you:

- Are hypersensitive or allergic to simvastatin, other statins (HMG-CoA reductase inhibitors) or any of the other ingredients in **CIPLA-SIMVASTATIN**.
- Have liver disease.
- Abnormal liver function test results. Please discuss this with your doctor if you are unsure.
- Are pregnant or breastfeeding, since the use of **CIPLA-SIMVASTATIN** may harm your baby (see **"Pregnancy and breastfeeding"**).
- Have been diagnosed with porphyria.
- Are also receiving treatment with 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.
- Are also receiving gemfibrozil for high cholesterol levels, ciclosporin to suppress your immune system or danazol for endometriosis.

Take special care with CIPLA-SIMVASTATIN:

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.

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.

Taking CIPLA-SIMVASTATIN with food and drink:

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**.

Use in pregnancy and breastfeeding:

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.

If you are pregnant or breastfeeding your baby while taking CIPLA-SIMVASTATIN, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

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

Taking other medicines with CIPLA-SIMVASTATIN:

See **"BEFORE YOU TAKE CIPLA-SIMVASTATIN"**.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CIPLA-SIMVASTATIN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

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.

HOW TO TAKE CIPLA-SIMVASTATIN:

Always take CIPLA-SIMVASTATIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with other people.

You must continue with your cholesterol-lowering diet while you take **CIPLA-SIMVASTATIN**. Swallow the tablets whole. 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 40 mg per day. You can take **CIPLA-SIMVASTATIN** with or without meals.

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

If you have the impression that the effect of **CIPLA-SIMVASTATIN** is too strong or too weak, please talk to your doctor or pharmacist.

If you take more CIPLA-SIMVASTATIN than you should:

If you take more **CIPLA-SIMVASTATIN** than you should, or if somebody else takes your medicine by mistake, you (or this other person) may experience any of the side-effects listed below.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control 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 compensate for the forgotten individual dose.

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 while taking CIPLA-SIMVASTATIN, please consult your doctor, pharmacist or other healthcare professional for advice.

The most serious side-effects with **CIPLA-SIMVASTATIN** that you should report to your doctor as a matter of urgency include the following:

- Those that occur frequently:
    - Fever, chills, painful coughing, skin ulcers, pain in the flank or blood in the urine or any other symptoms you think are due to a severe infection.
    - Palpitations or fainting spells.
    - Severe stomach pain with bloating and vomiting.
- Those that occur less frequently:
    - Allergic or hypersensitivity reactions that may present with severe swelling of the face, lips or tongue, or even whole body, skin rash

or hives, tightness of the chest or shortness of breath, itching, sensitivity to light, and fever.

    - Muscle pain or weakness (**"Take special care with CIPLA-SIMVASTATIN"**).

- Those that occur with unknown frequency:
    - Any skin rash with blister formation.
    - Yellow discolouration of the skin or whites of the eyes (see **"Take special care with CIPLA-SIMVASTATIN"**).

Other serious side-effects that you should report to your doctor as soon as possible include:

- Those that occur frequently:
    - Painful urination, pain over the bladder or frequent urination.
    - Pallor with shortness of breath or lack of energy.
    - Increased thirst, increased hunger and frequent urination (see **"Take special care with CIPLA-SIMVASTATIN"**).
    - Heartburn or reflux with pain over the upper part of the stomach.
    - Skin rash.
    - Swelling of the feet or ankles.
- Those that occur less frequently:
    - Pins and needles.
- Those that occur with unknown frequency:
    - Erectile dysfunction.

Other side-effects, which you should report to your doctor if they continue or become bothersome, include:

- Those that occur frequently:
    - Coughing, sneezing, runny nose or sore throat, pain over the sinuses.
    - Headache.
    - Inability to sleep.
    - Vertigo (a feeling of motion when one is standing/sitting still).
    - Constipation, nausea, vomiting, loose stools, flatulence (gas), indigestion, stomach pain, cramps.
    - Hair loss.
- Those that occur less frequently:
    - Dizziness, fatigue or unusual tiredness.
- Those that occur with unknown frequency:
    - Weight gain.
    - Depression.
    - Memory loss, forgetfulness, confusion.
    - Itching or any skin change, including nail or hair changes.

Please tell your doctor or pharmacist of any other undesirable effects you think may be due to taking **CIPLA-SIMVASTATIN**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF 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.

KEEP ALL MEDICINES OUT OF REACH AND SIGHT 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.

PRESENTATION OF CIPLA-SIMVASTATIN:

White opaque PVC/PVDC and aluminium foil blister strips of 10 tablets, packed in 30's.

IDENTIFICATION OF CIPLA-SIMVASTATIN:

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.

REGISTRATION NUMBERS:

CIPLA-SIMVASTATIN 10:	A40/7.5/0397
CIPLA-SIMVASTATIN 20:	A40/7.5/0398
CIPLA-SIMVASTATIN 40:	A38/7.5/0370
CIPLA-SIMVASTATIN 80:	A38/7.5/0371

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap, Mispel Street

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

06 October 2006