

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

S4

**SIMITRI, 145 mg/20 mg and 145 mg/40 mg, film-coated tablets**

**Fenofibrate/Simvastatin**

**Contains sugar:**

**SIMITRI 145/20 contains 160,1 mg lactose (as monohydrate) and 145 mg sucrose per film-coated tablet.**

**SIMITRI 145/40 contains 194,7 mg lactose (as monohydrate) and 145 mg sucrose per film-coated tablet.**

Read all of this leaflet carefully before you start taking SIMITRI.

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

#### **1. What SIMITRI is and what it is used for**

SIMITRI contains fenofibrate (belongs to the group called 'fibrates') and simvastatin (belongs to the group called 'statins'). They are both used to lower levels of total cholesterol, "bad" (low-density

lipoprotein (LDL)) cholesterol and fatty substances called triglycerides in the blood. In addition, they both raise levels of “good” (high-density lipoprotein (HDL)) cholesterol. Cholesterol is one of several fats found in your blood. Your total cholesterol is made up mainly of LDL and HDL cholesterol. LDL cholesterol can build up in the walls of your arteries and form plaque. Over time, this plaque build-up can lead to a clogging of your arteries. HDL cholesterol helps keep the LDL cholesterol from building up in the arteries and it protects against heart disease. Triglycerides are another fat in your blood that may raise your risk of having heart problems.

SIMITRI is used in adults at high risk of heart problems who have high blood levels of 2 types of fats (triglycerides and LDL cholesterol). It is given to lower triglycerides and increase HDL cholesterol in patients whose LDL cholesterol is controlled with simvastatin alone. You must follow a low-fat diet and exercise while taking SIMITRI.

## **2. What you need to know before you take SIMITRI**

### **Do not take SIMITRI**

- If you are hypersensitive (allergic) to fenofibrate or simvastatin or any of the other ingredients of SIMITRI (listed in section 6).
- If you are allergic to peanut, arachis oil, soy lecithin or related substances.
- If while taking other medicines, you have had an allergic reaction or skin damage from sunlight or UV light (these medicines include other fibrates and an anti-inflammatory medicine called ketoprofen).
- If you have liver problems.
- If you have gallbladder problems.
- If you have inflammation of the pancreas (with symptoms such as stomach pain/tenderness, fever, nausea (feeling sick) and vomiting (being sick)) which is not caused by high levels of fats in your blood.
- If you have moderate or severe kidney problems.
- If you are already taking the following medicines:
  - Itraconazole, ketoconazole, posaconazole, voriconazole (used to treat fungal infections).

- Nelfinavir, cobicistat (used to treat human immunodeficiency virus (HIV) infection).
- Boceprevir, telaprevir, glecaprevir, pibrentasvir, elbasvir, grazoprevir (used to treat chronic hepatitis C (an ongoing viral infection that damages the liver)).
- Erythromycin, clarithromycin, telithromycin (used to treat bacterial infections).
- Nefazodone (used to treat depression).
- Gemfibrozil (used to lower cholesterol and triglycerides in the blood).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Danazol (used to treat endometriosis (a condition in which the tissue that lines the womb grows in other areas of the body)).
- If you are under 18 years of age.
- If you are pregnant or breastfeeding.
- If you have a history of muscle problems while taking fenofibrate and/or simvastatin as in SIMITRI.
- If you are already taking the following medicines:
  - Amiodarone (used to treat heart rhythm disorders).
  - Amlodipine (used to treat high blood pressure).
  - Verapamil, diltiazem (used to treat high blood pressure and angina (chest pain)).

## **Warnings and precautions**

### **Take special care with SIMITRI**

- If you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this. Your doctor may do a blood test to check your muscles before and after starting treatment with SIMITRI.
- If you are taking a medicine called fusidic acid (used to treat bacterial infections).
- If you have an underactive thyroid gland (hypothyroidism).
- If you or a close family member have a muscle problem which runs in the family.
- If you are due to have an operation. You may need to stop taking SIMITRI for a short time.
- If you drink large amounts of alcohol. Your doctor should do a blood test before you start taking SIMITRI and after you have started taking SIMITRI. This is to check how well your liver

is working.

- If you have inflammation of the pancreas (with symptoms such as stomach pain/tenderness, fever, nausea (feeling sick) and vomiting (being sick)) which is caused by high levels of fats in your blood.
- If you have mild kidney problems. Do not take SIMITRI if you have moderate to severe kidney problems (see Do not take SIMITRI).
- If you develop a lung disease with symptoms such as difficulty breathing, cough, tiredness, weight loss and fever, while taking SIMITRI. Stop taking SIMITRI and contact your health care provider immediately.
- While you are taking SIMITRI 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/or have high blood pressure.
- If you have a history of pulmonary embolism (a blood clot in the lung characterised by symptoms such as shortness of breath, chest pain, cough and fast heartbeat).

### **Children and adolescents**

SIMITRI must not be given to children and adolescents below 18 years of age.

### **Other medicines and SIMITRI**

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

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Itraconazole, ketoconazole, posaconazole, fluconazole (used to treat fungal infections).
- Erythromycin, clarithromycin, telithromycin (used to treat bacterial infections).
- Nelfinavir, cobicistat (used to treat human immunodeficiency virus (HIV) infection).
- Nefazodone (used to treat depression).
- Verapamil, diltiazem (used to treat high blood pressure and angina (chest pain)).
- Danazol (used to treat endometriosis (a condition in which the tissue that lines the womb grows in other areas of the body)).

- Ciclosporin (used to prevent organ rejection after a transplant).
- Amiodarone (used to treat heart rhythm disorders).
- Amlodipine (used to treat high blood pressure).
- Elbasvir, grazoprevir (used to treat chronic hepatitis C (an ongoing viral infection that damages the liver)).
- Gemfibrozil (used to lower cholesterol and triglycerides in the blood).
- Niacin (nicotinic acid) (used to prevent and treat niacin deficiency (pellagra)).
- Fusidic acid (used to treat bacterial skin and eye infections).
- Colchicine (used to treat acute gout attacks).
- Vitamin K antagonists (used to thin your blood and prevent blood clots from forming).
- Glitazones (used to treat high blood sugar levels).
- Rifampicin (used to treat tuberculosis (TB)).

### **SIMITRI with drink**

Do not drink grapefruit juice while taking SIMITRI.

### **Pregnancy and breastfeeding**

Do not take SIMITRI if you are pregnant or breastfeeding (see Do not take SIMITRI).

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 SIMITRI.

### **Driving and using machines**

SIMITRI may cause side effects such as dizziness and blurred vision and can affect your ability to drive a vehicle and use machines (see 4. Possible side effects). It is not always possible to predict to what extent SIMITRI may interfere with your daily activities. Do not drive a vehicle or operate machines until you are aware of the measure to which SIMITRI affects you.

**IMITRI contains lactose, sucrose, sodium and the colourant Sunset Yellow**

IMITRI contains sugar, lactose (as monohydrate) and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking IMITRI.

IMITRI contains less than 1 mmol sodium (23 mg) per one tablet, that is to say essentially sodium-free.

IMITRI 145/20 contains the colourant Sunset Yellow (E110) that may cause allergic reactions.

**3. How to take IMITRI**

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

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

The usual dose is one tablet per day.

Your doctor will determine your dose, depending on your condition, your current treatment and your personal risk status.

You can take IMITRI with or without food.

Swallow the whole tablet with a glass of water. Do not crush or chew the tablet.

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

**If you take more IMITRI 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 IMITRI**

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take IMITRI at the next regularly scheduled time.

Do not take a double dose to make up for a forgotten individual doses.

#### **4. Possible side effects**

SIMITRI can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

- Bleeding and bruising more easily than normal.
- Yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems (also called jaundice).
- Passing more or less urine than normal for you.
- Changes in the way your heart beats, for example, if you notice it beating faster or skipping beats.
- Signs of recurrent infections such as fever or sore throat.
- Chest pain.
- A condition in which your body does not produce enough insulin or else your body tissues are not able to use the insulin present, this leads to high sugar levels in the blood.
- Throbbing or cramping pain in 1 leg (rarely both legs), usually in the calf or thigh.
- Interstitial lung disease (shortness of breath, dry cough, extreme tiredness/weakness, loss of appetite).

- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Muscle pain in the shoulders, thighs or lower back, muscle weakness or trouble moving arms and legs.

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

Tell your doctor as soon as possible if you notice any of the following:

*Frequent side effects:*

- Viral infection that affects your nose, throat and airways.
- Diarrhoea, cramps, nausea (feeling sick), vomiting (being sick).
- Stomach pain, excessive gas in your stomach.

*Less frequent side effects:*

- Inability to sleep.
- Headache, dizziness, memory loss.
- Tingling or numbness in your hands or feet, dropping things from your hands regularly, feeling of weakness or heaviness in your arms and legs, sharp stabbing pains.
- Blurred visions, not be able to see objects at a distance.
- Stomach pain that radiates to your back.
- Constipation, pain or burning in the stomach (dyspepsia).
- Hair loss (temporary).
- Sores or ulcers inside your mouth.
- Pain in a muscle or group of muscles.
- Breast enlargement in men.
- Lack of sex drive.
- Abnormal physical weakness or lack of energy.

*Side effects with frequency unknown:*

- Nightmares, depression.

- Inability to develop or maintain an erection.

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 SAHPRA website.

By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME].

Abbott Laboratories South Africa Pharmacovigilance: [pv.south-africa@abbott.com](mailto:pv.south-africa@abbott.com).

## **5. How to store SIMITRI**

- Store all medicines out of the reach of children.
- Store at or below 30 °C.
- Do not use SIMITRI after the expiry date stated on the carton and the blister strip.
- 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 SIMITRI contains**

The active substances are fenofibrate and simvastatin.

SIMITRI 145/20: Each film-coated tablet contains 145 mg fenofibrate and 20 mg simvastatin.

SIMITRI 145/40: Each film-coated tablet contains 145 mg fenofibrate and 40 mg simvastatin.

The other ingredients are ascorbic acid (E300), butylhydroxyanisole (E320), citric acid monohydrate (E330), crospovidone (E1202), docusate sodium, hypromellose (E464), iron oxide red (E172), iron oxide yellow (E172) (only in SIMITRI 145/20), lactose monohydrate, lecithin

(derived from soy bean (E322)), magnesium stearate (E572), silicified microcrystalline cellulose (consists of cellulose, microcrystalline and silica, colloidal anhydrous), sodium laurilsulfate, starch, poly (vinyl alcohol), Sunset Yellow (E110) (only in SIMITRI 145/20), partially hydrolysed (E1203), pregelatinised (maize), sucrose, talc (E553b), titanium dioxide (E171), xanthan gum (E415).

### **What SIMITRI looks like and contents of the pack**

SIMITRI 145/20: Tan, oval, film-coated tablet, with 145/20 on one side.

SIMITRI 145/40: Brick-red, oval, film-coated tablet, with 145/40 on one side.

Alu/Alu blister strip containing 10 tablets. One (1), Three (3), six (6) or nine (9) blister strips are packed in an outer cardboard carton.

Pack sizes: 10, 30,60 and 90.

Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

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