PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LESTAVOR® 10 film-coated tablets

LESTAVOR® 20 film-coated tablets

LESTAVOR® 40 film-coated tablets

LESTAVOR® 80 film-coated tablets

Atorvastatin calcium

Contains lactose

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

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

2. What you need to know before you take LESTAVOR

3. How to take LESTAVOR

4. Possible side effects

5. How to store LESTAVOR

6. Contents of the pack and other information

1. What LESTAVOR is and what it is used for

LESTAVOR belongs to a group of medicines known as lipid (fat) regulating medicines, also referred to as statins.

LESTAVOR is used, together with a low fat diet, to reduce your levels of cholesterol and triglycerides (fat in the blood).

It is important to continue with your low fat diet and lifestyle changes while taking LESTAVOR.

2. What you need to know before you take LESTAVOR

Do not take LESTAVOR if you:

- are hypersensitive (allergic) to atorvastatin, any other statin, or any of the ingredients of LESTAVOR (see section 6: "*What LESTAVOR contains*");
- have liver problems;
- have unexplained abnormal blood tests for liver function;
- drink excessive amounts of alcohol;
- are a woman able to have children, and are not using reliable contraception;
- are pregnant or breastfeeding your baby;
- are also taking rifampicin (an antibiotic used for certain types of bacterial infections and tuberculosis) or diltiazem (used to treat high blood pressure and to control chest pain). See also section 2: "*Other medicines and LESTAVOR*".

Do not drink grapefruit juice if you are taking LESTAVOR (see **"***LESTAVOR with food and drink"* below).

Warnings and precautions

The presence of other medical problems may affect the use of LESTAVOR. Talk to your doctor, pharmacist or health care provider before taking LESTAVOR if you:

- have liver or kidney disease;
- have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) – statins, like LESTAVOR, may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4);
- or your family have a history of any repeated or unexplained muscle aches or pains. Your doctor will refer you for blood tests before, and possibly during, your LESTAVOR treatment, to predict your risk of muscle related side effects;
- have previously experienced muscle problems while being treated with other statins or other lipid-lowering medicines;
- have had a previous stroke with bleeding into the brain;
- had an organ transplant and are being treated with immunosuppressants (medicines that suppress activity of the immune system);
- are a heavy drinker of alcohol;
- have a severe acute infection;
- have low blood pressure (hypotension);
- have uncontrolled seizures;
- have major surgery or trauma;
- develop jaundice (yellowish discolouration of the whites of the eyes, skin, and mucous membranes caused by deposition of bile salts in these tissues).

Children and adolescents

Use in children is not recommended, as safety and efficacy have not been established.

Other medicines and LESTAVOR

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

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of LESTAVOR with these medicines may cause undesirable interactions. Some of the medicines that may interact with LESTAVOR are:

- medicines used to alter the way your immune system works, e.g. ciclosporin;
- certain antibiotics, antiviral or antifungal medicines, e.g. itraconazole, ketoconazole, erythromycin, clarithromycin, HIV-protease inhibitors;
- fusidic acid – an antibiotic medicine used for various skin or eye infections;
- medicines that prevent blood clotting (e.g. warfarin) – you may find that you bleed more easily;
- medicines used to regulate your heart rhythm e.g. digoxin, amiodarone;
- other medicines that help lower cholesterol, e.g. cholestyramine, colestipol, fibrates, gemfibrozil or nicotinic acid;
- some calcium channel blockers used for chest pain or high blood pressure, e.g. verapamil, diltiazem;
- antacids (indigestion products);
- oral contraceptives.

Before you begin using (or taking) any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are taking LESTAVOR, check with your doctor, nurse or pharmacist.

LESTAVOR with food and drink

You can take LESTAVOR tablets with or without food.

LESTAVOR should not be taken with grapefruit juice, or other grapefruit products in large amounts.

Pregnancy and breastfeeding

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.

LESTAVOR should not be used if you are pregnant or breastfeeding.

If you are trying to become pregnant, you should inform your doctor and stop taking LESTAVOR one month before you plan to conceive.

Driving and using machinery

LESTAVOR may cause dizziness, drowsiness or related problems. Make sure you know how you react to LESTAVOR before you drive or use machines that require you to be alert.

LESTAVOR contains lactose monohydrate

LESTAVOR contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LESTAVOR.

3. How to take LESTAVOR

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

Always take LESTAVOR 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 before, and during, treatment with LESTAVOR.

You can take LESTAVOR tablets with or without food. You should not take LESTAVOR with grapefruit juice, or other grapefruit products in large amounts.

The usual starting dose is 10 mg LESTAVOR daily in adults. This may be increased by your doctor until you are taking the amount you need to get the required response.

Your doctor will tell you how long your treatment with LESTAVOR will last. Do not stop treatment without talking to your doctor.

If you have the impression that the effect of LESTAVOR is too strong or too weak, you should talk to your doctor or pharmacist.

If you take more LESTAVOR than you should

You may experience an increase in side effects and their frequency. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take LESTAVOR

If you miss a dose of LESTAVOR, take it as soon as you remember. However, if it is

almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LESTAVOR can have side effects.

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

Stop taking LESTAVOR and tell your doctor immediately if you experience any of the following side effects:

- your muscles become weak, painful and tender, especially if you also feel unwell or have a high temperature or if your muscles start cramping. In some cases, this could progress to a serious and potentially life-threatening condition called rhabdomyolysis (a condition of muscle disintegration that can lead to kidney failure).
- loss of appetite, stomach pain, dark-coloured urine, yellow colouring of the skin or the white of the eyes.
- allergic reactions (including swelling of the face, eyelids, lips, tongue, throat; difficulty in breathing and swallowing, hives and itching).
- chest pain.

If any of the above happens, stop taking LESTAVOR and tell your doctor immediately or go to the casualty department at your nearest hospital. These are all very serious side effects. You may need urgent medical attention or hospitalisation.

The following side effects occur frequently; consult your doctor if the side effects persist or become bothersome: Trouble in sleeping; dizziness; headache; abnormal skin sensations (as tingling or tickling or itching or burning); a reduced sense of touch or sensation; constipation; diarrhoea; flatulence; heartburn; abdominal or stomach pain and cramps; nausea, indigestion; skin rash; an intense itching sensation; muscle pain; pain in a joint or joints; back pain; fatigue (tiredness); feeling weak, lacking energy or strength.

The following side effects occur less frequently: If you are pale, feel tired, get frequent infections or your blood takes longer to clot, you may have a lower than normal number of red blood cells, white blood cells or platelets in the blood; low or high blood sugar (ask your doctor how often you should have your blood tested and what tests you need to have done); weight gain; numbness, tingling, or pain, usually in the hands and feet, caused by damage to the peripheral nerves; partial or total loss of memory, forgetfulness, confusion; blurred vision; ringing sound in the ears; loss of hearing; taste disturbances; vomiting; inflammation of the pancreas (you may feel sick, feverish and notice a gradual or sudden pain in the upper abdomen); loss of appetite; inflammation of the liver (you may feel sick, tired, have dark urine, unusually light coloured stools, yellowing of the skin and whites of the eyes); liver failure (you may for example feel sick, tired, have diarrhoea and a swollen abdomen); decreased sexual ability; excessive development of the breasts in males; loss of hair; hives; muscle disease; muscle weakness, muscle pain, muscle cramps; inflammation of muscle tissue; swelling of the extremities; sinusitis (inflammation of the nasal sinus membranes), pharyngitis (sore, inflamed throat); feeling of general discomfort or uneasiness, increases in blood sugar levels.

The following side effects' frequency is unknown: Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing) and ocular myasthenia (a disease causing eye muscle weakness).
Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

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. This includes any possible side effects not listed in this leaflet. 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 this medicine.

5. How to store LESTAVOR

Store in the original packaging (in the carton) at or below 30 °C.
Do not store your medicine in the bathroom.
Do not use LESTAVOR after the expiry date printed on the label, container or blister.
Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
STORE ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

What LESTAVOR contains

The active substance is atorvastatin calcium.

LESTAVOR 10: Each film-coated tablet contains atorvastatin calcium equivalent to 10 mg atorvastatin.

LESTAVOR 20: Each film-coated tablet contains atorvastatin calcium equivalent to 20 mg atorvastatin.

LESTAVOR 40: Each film-coated tablet contains atorvastatin calcium equivalent to 40 mg atorvastatin.

LESTAVOR 80: Each film-coated tablet contains atorvastatin calcium equivalent to 80 mg atorvastatin.

LESTAVOR 10, 20, 40 & 80 film-coated tablets also contain the following inactive ingredients: activated attapulgite, Microcelac 100 (consisting of lactose monohydrate and microcrystalline cellulose), microcrystalline cellulose, pregelatinised starch, hydroxypropyl cellulose, magnesium stearate, silica colloidal anhydrous, and Opadry White (consisting of hypromellose, lactose monohydrate, polyethylene glycol and titanium dioxide).

Contains lactose (milk sugar) – see section 2: "*LESTAVOR contains lactose monohydrate*".

What LESTAVOR looks like and contents of the pack

LESTAVOR 10: White oval biconvex film-coated tablets, approximately 10,1 x 5,6 mm and 3,7 mm in thickness.

LESTAVOR 20: White oval biconvex film-coated tablets with a non-functional breakline on one side, approximately 12,7 x 6,7 mm and 4,6 mm in thickness.

LESTAVOR 40: White oblong biconvex film-coated tablets, approximately 19,4 x 7,8 mm and 4,7 mm in thickness.

LESTAVOR 80: White oblong biconvex film-coated tablets with a non-functional breakline on one side, approximately 22,8 x 10,9 mm and 5,7 mm in thickness.

LESTAVOR film-coated tablets are packed in packs of 28 (4 blisters of 7 film-coated tablets) or 30 (3 blisters of 10 film-coated tablets) in Aluminium/ Aluminium blisters strips in a cardboard carton. Not all pack sizes are necessarily marketed.

Holder of the Certificates of Registration

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