PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

VASTOR 10 mg (film-coated tablets)

Contains sugar: Lactose anhydrous 42,5 mg

VASTOR 20 mg (film-coated tablets)

Contains sugar: Lactose anhydrous 85 mg

VASTOR 40 mg (film-coated tablets)

Contains sugar: Lactose anhydrous 170 mg

VASTOR 80 mg (film-coated tablets)

Contains sugar: Lactose anhydrous 340 mg

Atorvastatin

Read all of this leaflet carefully before you start taking VASTOR

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

1. What VASTOR is and what it is used for

What VASTOR is:

VASTOR belongs to a group of medicines known as lipid (fat) regulating medicines commonly known as statins.

What it is used for:

VASTOR is used to lower lipids known as cholesterol and triglycerides in the blood when a low-fat diet and lifestyle changes on their own have failed.

Remember to continue with your diet and lifestyle changes while you are taking VASTOR.

2. What you need to know before you take VASTOR

Do not take VASTOR

- If you are hypersensitive (allergic) to atorvastatin or to medicines of the same class (statins or lipid lowering medicines), or any of the other ingredients of VASTOR (listed in section 6).
- If you are receiving treatment for your immune system such as ciclosporin (see Other medicines and VASTOR).
- If you are pregnant, trying to become pregnant or breastfeeding your baby.
- If you have or ever had a disease which affects the liver.
- If you have had any unexplained abnormal blood test results for liver function.
- If you have any muscle disease.
- If you are taking the following:
    - Rifampicin: an antibiotic used to treat several types of bacterial infections, including tuberculosis (TB).
    - Diltiazem: medicine used to treat high blood pressure and to control angina (chest pain).
    - Hepatitis C antivirals glecaprevir/pibrentasvir.
    - If you drink grapefruit juice.

Warnings and precautions

Take special care with VASTOR:

- If you experience any of the following symptoms: unusual fatigue or weakness, loss of appetite, stomach pain, dark-coloured urine, or yellowing of the skin or the white of the eyes, you should

notify your health care professional right away. Serious liver problems may occur. Your doctor will carry out a liver function test before treatment starts and if needed thereafter.

- If you have ever had any type of stroke. Tell your doctor will need to consider this in deciding the best treatment and dose for you.
- If you have any kidney disorders.
- If you have an under-active thyroid gland.
- If you have or had repeated or unexplained muscle aches or pains, or if you have a personal history or family history of muscle problems.
- If you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other statins or fibrate medicines).
- If you have diabetes or if you have a risk of developing diabetes and take VASTOR. Your doctor will monitor you on a regular basis.
- If you experience forgetfulness and confusion. Tell this to your doctor. These symptoms will disappear after stopping treatment with VASTOR.
- If you are taking any of the following medicines as the risk of muscle-related side effects is increased if taken together with VASTOR (see Other medicines and VASTOR):
    - Colchicine (used to treat gout, a kind of arthritis).
    - Fibric acid derivatives (a class of medicines also used to lower blood fat levels).
    - Telaprevir or boceprevir (used to treat hepatitis C).
    - Saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir and fosamprenavir plus ritonavir (combination of protease inhibitors used to treat HIV).
    - Azole antifungal medication (used to treat fungal infections).
    - Fusidic acid or erythromycin (antibiotics used to treat bacterial infections). If you are taking or have taken fusidic acid orally or by injection in the last 7 days. The combination of fusidic acid and VASTOR can lead to serious muscle problems (rhabdomyolysis).
    - Protease inhibitors (a class of medicines used to treat or prevent infection by viruses).
    - If you are taking medicine that contains statins, such as VASTOR, you might be at risk of developing weakness of skeletal muscles that control body movement (arms and legs) and

breathing (myasthenia gravis) or weakness of the muscles that control eye and eyelid movement (ocular myasthenia).

Also take special care with VASTOR if you:

- Regularly drink a large amount of alcohol.
- Are older than 70 years.

Before you have any medical tests, tell the doctor that you are using VASTOR.

Tell your doctor if you have ever had any type of stroke; your doctor will need to consider this in deciding the best treatment and dose for you.

Tell your doctor if you have ever had a serious liver injury or jaundice (yellow discolouration of skin or whites of the eyes) occurs.

If you experience unexplained muscle pain, tenderness or weakness, especially if accompanied by fever or a general feeling of being unwell, tell your doctor. Your doctor may need to carry out a blood test before and possibly during your VASTOR treatment.

If you have diabetes or are at risk of developing diabetes while you are on this medicine, your doctor will monitor you closely. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight or have high blood pressure.

Other medicines and VASTOR

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

There are some medicines that may change the effect of VASTOR, or their effect may be changed by VASTOR. This type of interaction could make one or both of the medicines less effective. Alternatively, it could increase the risk or severity of side effects, including the important condition known as rhabdomyolysis (serious muscle pain and weakness often associated with fever). Your doctor will consider this in deciding upon your dose of VASTOR.

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

- Antifungal medicines e.g. clotrimazole, itraconazole, ketoconazole may increase VASTOR blood levels.
- Certain antibiotics medicines e.g. clarithromycin, telithromycin and rifampicin (see Do not take VASTOR).

- Ciclosporin (medicine used to alter the way your immune system works) (see Do not take VASTOR).
- Other medicines to regulate lipid (fat) levels e.g. fibric acid derivatives, colestipol, niacin (nicotinic acid) may reduce VASTOR blood levels.
- Digoxin (medicine to regulate your heart rhythm) may increase digoxin levels in the blood.
- Diltiazem (medicine for angina or high blood pressure) may increase VASTOR blood levels (see Do not take VASTOR).
- Efavirenz (medicine used in the treatment of HIV) may reduce VASTOR blood levels.
- Erythromycin (an antibiotic medicine) may increase VASTOR blood levels.
- Gemfibrozil (medicine to regulate lipid levels).
- Fusidic acid (this is a type of antibiotic medicine). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart VASTOR. Taking VASTOR with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis) (see section Take special care with VASTOR).
- Oral antacid suspension containing magnesium and aluminium may reduce VASTOR blood levels.
- Oral contraceptives which contain norethindrone and ethinyl estradiol (your doctor may want to change your oral contraceptive treatment). VASTOR may increase blood levels of the respective contraceptives.
- Nicotinic acid (nutritional supplement).
- Protease inhibitors (medicines used in the treatment of HIV e.g. nelfinavir) may increase VASTOR blood levels.
- Rifampicin, an antibiotic used to treat several types of bacterial infections, including, tuberculosis (TB), may reduce VASTOR blood levels (see Do not take VASTOR).
- Other medicines known to interact with VASTOR include warfarin (which reduces blood clotting), antacids (indigestion products containing aluminium or magnesium), ezetimibe (which lowers cholesterol) and phenazone (a painkiller).
- Telaprevir and boceprevir (used to treat hepatitis C) and the combination of elbasvir/grazoprevir, ledipasvir/sofosbuvir.
- Saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir,

fosamprenavir and fosamprenavir plus ritonavir, nelfinavir (combination of protease inhibitors used to treat HIV).

- Colchicine (used to treat gout, a kind of arthritis).
- Letermovir, a medicine that helps stop you from getting ill from cytomegalovirus.
- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir.
- St John's wort.
- Grapefruit juice: do not drink this while receiving treatment with VASTOR as it may increase levels of VASTOR (see VASTOR with food, drink and alcohol).

VASTOR with food, drink and alcohol

Do not drink grapefruit juice while taking VASTOR as it may interact with VASTOR and may increase the levels of VASTOR (see Do not take VASTO').

Pregnancy, breastfeeding and fertility

You should not take VASTOR if you are pregnant or breastfeeding your baby or if you are not using suitable preventative measures to avoid getting pregnant.

If you are pregnant or breastfeeding your baby, 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 VASTOR.

You should stop VASTOR treatment for at least one month before planning a pregnancy.

Driving and using machines

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

VASTOR may cause dizziness, confusion or other related problems. Make sure you know how you react to VASTOR before you drive or use any machines that require you to be alert.

VASTOR contains lactose

VASTOR contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take VASTOR.

3. How to take VASTOR

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

You will be placed on a standard cholesterol-lowering diet before receiving VASTOR and should continue on this diet during treatment with VASTOR.

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

The usual dose is:

- The usual starting dose is 10 mg once a day in adults and children aged 10 years and older.
- Your doctor will tell you how long your treatment with VASTOR will last.
- Doses will be individualised by your doctor according to your requirements and response.
- Adjustment of dosage should only be made by your doctor after an interval of 4 weeks or more.
- The maximum recommended dose is 40 mg once a day.
- Doses may be taken at any time of day, with or without food.
- Taking your tablet at the same time each day will have the best effect on your cholesterol levels. It will also help you remember when to take the tablet.

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

Children

Treatment experience in paediatrics is limited.

If you take more VASTOR than you should

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

If you forget to take VASTOR

If you missed a dose, take it as soon as possible. However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule.

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

4. Possible side effects

VASTOR can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes or genitals, fever or skin rash with pink-red blotches especially on palms of hands or soles of feet which may blister.
- Muscle weakness, tenderness, pain or rupture or red-brown discolouration of urine and particularly, if at the same time, you feel unwell or have a high temperature. It may be caused by an abnormal muscle breakdown (rhabdomyolysis). The abnormal muscle breakdown does not always go away, even after you have stopped taking VASTOR, and it can be life-threatening and lead to kidney problems.

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

- Abdominal pain and vomiting as this could be caused by inflammation of the pancreas.
- Your skin and whites of your eyes get yellow.
- Chest pain.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Allergic reactions, skin rashes.

- Headache, dizziness, numbness or tingling in the fingers and toes.
- Nausea, diarrhoea, stomach pain, indigestion, constipation, wind, belching.
- Joint pain, muscle pain and back pain.
- Lack or loss of strength, infection.

The following side effects have been reported less frequently:

- Blood disorders (reduction of red blood cells, decrease in blood platelets).
- Weight gain, changes in blood sugar levels, loss of appetite.
- Change in sense of taste, loss of memory, forgetfulness, and confusion.
- Ringing in the ears or hearing loss.
- Fluid retention.
- Liver problems such as hepatitis, jaundice (yellowing of the skin).
- Hair loss, various skin disorders.
- Disease of a muscle, inflammation of a muscle, muscle cramps.
- Sexual difficulties.
- Fatigue.
- Accidental injury, sore muscle tendons that may rupture.
- Nosebleed.
- Urine tests that are positive for white blood cells.
- Tendon injury.
- Gynaecomastia (breast enlargement in men).

The following side effects have been reported but the frequency is unknown:

- Sleeplessness.
- Reductions of sensation to pain or touch.
- Stuffy or runny nose due to inflammation, sore throat.
- Weakness of skeletal muscles that control body movement (arms and legs) and breathing (myasthenia gravis).
- Weakness of the muscles that control eye and eyelid movement (ocular myasthenia).

Possible side effects reported with some statins such as VASTOR (medicines of the same type):

- Blood tests may also show changes in your blood sugar levels and changes in your muscles and

liver.

- Depression.
- Breathing problems including persistent coughing and/or shortness of breath or fever.
- Diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

Additional side effects reported after the marketing of VASTOR include:

- Cognitive impairment (e.g. memory loss, forgetfulness, memory impairment and confusion).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions 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 VASTOR.

5. How to store VASTOR

Store all medicines out of reach of children.

- Store in a cool and dry place at or below 25 °C.
- Do not remove blisters from carton until required for use.
- The HDPE bottles must be kept tightly closed.
- Store in the original container/package.
- Keep the container in the outer carton.
- Do not store in a bathroom.

6. Contents of the pack and other information

What VASTOR contains

- The active substance is:

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

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

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

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

- The other ingredients are:

  Tablet core: Colloidal anhydrous silica (Aerosil 200), croscarmellose sodium, hydroxypropyl cellulose, L-arginine, lactose anhydrous, magnesium stearate, microcrystalline cellulose, sodium carbonate anhydrous.

  Film-coat: Opadry AMB white OY-B-28920.

What VASTOR looks like and contents of the pack

What VASTOR looks like:

VASTOR 10 mg: White, oval, biconvex, film-coated tablet, plain on one side and debossed ‘10’ on the other side.

VASTOR 20 mg: White, oval biconvex, film-coated tablet with break line on one side and debossed ‘20’ on the other side.

VASTOR 40 mg: White, oval, biconvex film-coated tablet with break line on one side and debossed ‘40’ on the other side.

VASTOR 80 mg: White, oval, biconvex, film-coated table with break line on one side and debossed ‘80’ on the other side.

Contents of the pack:

HDPE bottle pack (without stabilox)

High-density polyethylene (HDPE) bottle pack comprises of white opaque HDPE bottle provided along with a polypropylene (PP) screw cap. The HDPE bottle is placed in a carton (excl. tender).

Pack sizes: 28’s, 30’s, 90’s and 500’s.

HDPE bottle pack (with activated carbon)

High-density polyethylene (HDPE) bottle pack comprises of white opaque HDPE bottle with desiccant (activated Carbon Minipax) sachet provided with a polypropylene (PP) screw cap. The HDPE bottle is

placed in a carton (exc. tender).

Pack sizes: 28’s, 30’s 90’s and 500’s.

Cold form blister pack

Cold form blister pack (marketable pack) comprises of cold form laminate on one side [aluminium foil laminated to oriented polyamide on one side and laminated to PVC on other side (i.e. OPA/Al/PVC)] and hard tempered aluminium foil coated with heat seal lacquer on the other side. The blisters are placed in a carton.

7 or 10 tablets per blister strip packed as 28’s or 30’s.

PVC/Aclar blister pack

PVC/Aclar blister pack comprises of clear, transparent, PVC laminated with Aclar on one side and hard tempered aluminium foil coated with VMCH heat seal lacquer on the other side. The blisters are placed in a carton.

7, 10 or 15 tablets per blister strip packed as 28’s or 30’s.

Not all packs may be marketed.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

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