APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

HAXTOVAT 10 mg film-coated tablets

HAXTOVAT 20 mg film-coated tablets

HAXTOVAT 40 mg film-coated tablets

HAXTOVAT 80 mg film-coated tablets

HAXTOVAT 10 mg: Each film-coated tablet contains 10 mg of Atorvastatin equivalent to 10,825 mg of Atorvastatin calcium Trihydrate USP.

HAXTOVAT 20 mg: Each film-coated tablet contains 20 mg of Atorvastatin equivalent to 21,649 mg of Atorvastatin calcium Trihydrate USP.

HAXTOVAT 40 mg: Each film-coated tablet contains 40 mg of Atorvastatin equivalent to 43,299 mg of Atorvastatin calcium Trihydrate USP**.**

HAXTOVAT 80 mg: Each film-coated tablet contains 80 mg of Atorvastatin equivalent to 86,597 mg of Atorvastatin calcium Trihydrate USP.

Contains sugar “lactose monohydrate”

HAXTOVAT 10 mg Each film-coated tablets contains 32,500 mg Contains sugar “lactose monohydrate”

HAXTOVAT 20 mg: Contains sugar “lactose monohydrate”

Each film-coated tablets contains 65,000 mg lactose monohydrate

HAXTOVAT 40 mg: Each film-coated tablet contains 34,575 mg lactose monohydrate

HAXTOVAT 40 mg: Each film-coated tablet contains 46,100 mg lactose monohydrate

Read all of this leaflet carefully before you start taking **HAXTOVAT**

- 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.
- **HAXTOVAT** 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 HAXTOVAT is and what it is used for

HAXTOVAT contains the active substance atorvastatin calcium trihydrate, equivalent to 10/20/40/80 mg atorvastatin respectively.

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

HAXTOVAT lowers cholesterol in your blood. It lowers the LDL-C ("bad" cholesterol) and triglycerides in your blood. It can raise your HDL-C ("good" cholesterol) as well. **HAXTOVAT** is for adults and children over 10 years of age whose cholesterol does not come down enough with exercise and a low-fat diet alone.

HAXTOVAT can lower risk of heart disease and disorders of the blood vessels of the brain, which are conditions due to reduced blood supply, in patients who have multiple risk factors for heart disease, such as smoking, high blood pressure (hypertension), diabetes, low HDL-C, or a family history of early coronary heart disease. **HAXTOVAT** can reduce heart events in patients with heart disease and high cholesterol levels.

2.What you need to know before you take HAXTOVAT

Do not take HAXTOVAT:

- if you are hypersensitive (allergic) to atorvastatin or any of the other ingredients of **HAXTOVAT** (listed in section 6).
- If you are pregnant, trying to fall pregnant or breastfeeding.
- If you are able to have children and are not using adequate contraceptive measures.
- If you have or have had any liver disease or any unexplained abnormal blood tests for liver function.
- If you are taking rifampicin, an antibiotic, for an infection.
- If you are taking diltiazem, a calcium channel blocker, for angina or high blood pressure.
- If you drink grapefruit juice.

Warnings and precautions

Take special care with **HAXTOVAT**:

Tell your doctor or health care provider before taking **HAXTOVAT**:

- If you have kidney problems.
- If you have an underactive thyroid gland (hypothyroidism).
- If you have muscle disorders or if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other “statins” or “fibrate” medicines).
- If you drink excessive amounts of alcohol and/or have a history of liver disease.
- If you are taking any of the following medication as the risk of muscle-related side effects is increased if taken together with **HAXTOVAT**

- Colchicine (used to treat gout, a kind of arthritis).
- Vitamin B3.
- 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).
- Immunosuppressive medicines (medicines that inhibit or prevent activity of the immune system).
- Azole antifungal medication (used to treat fungal infections).
- Fusidic acid or erythromycin (antibiotics used to treat bacterial infections).
- If you have diabetes as **HAXTOVAT** can lead to high blood sugar.
- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes (haemorrhagic stroke)
- if you have severe respiratory failure
- if you have a lung condition causing breathing difficulties, shortness of breath, or a dry couch (interstitial lung disease)

Tell your doctor immediately if you experience these symptoms.

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 **HAXTOVAT** treatment to predict your risk of muscle-

related side effects.

If you have muscle disorders or if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other “statins” or “fibrate” medicines).

- Protease inhibitors (a class of medicines used to treat or prevent infection by viruses.

Children and adolescents

Experience in paediatrics is limited

Other medicines and HAXTOVAT

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 **HAXTOVAT**, or their effect may be changed by **HAXTOVAT**. 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 **HAXTOVAT**.

Some medicines that may interact with **HAXTOVAT** include:

- Medicines used to modulate immune response e.g. ciclosporin.
- Certain antibiotics or antifungal medicines e.g. erythromycin, clarithromycin, azithromycin, clotrimazole, rifampicin and itraconazole.
- Other medicines to regulate lipid (fat) levels e.g. fibric acid derivatives, colestipol, niacin (nicotinic acid).
- Some calcium channel blockers used for angina or high blood pressure e.g. diltiazem and amlodipine.
- Medicines to regulate your heart rhythm e.g. digoxin.
- Protease inhibitors used in the treatment of HIV e.g. nelfinavir.

- Efavirenz used in the treatment of HIV.
- Other medicines known to interact with **HAXTOVAT** include warfarin (which reduces blood clotting), oral contraceptives, antacids (indigestion products containing aluminium or magnesium)
- Fucidic 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
- Telaprevir and boceprevir (used to treat hepatitis C).
- 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).

Taking HAXTOVAT with food and drink:

Grapefruit juice should be avoided when taking **HAXTOVAT** as this combination can result in an undesirable interaction.

Pregnancy, breastfeeding and fertility

Do not take **HAXTOVAT**:

- If you are pregnant, trying to fall pregnant or breastfeeding.
- If you are able to have children and are not using adequate contraceptive measures.
- 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 healthcare professional for advice before taking this medicine

Driving and using machines

HAXTOVAT has negligible influence on the ability to drive and use machines.

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

HAXTOVAT contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars such as lactose, contact your doctor before taking **HAXTOVAT**.

3. How to take HAXTOVAT

Do not share medicines prescribed for you with any other person. Always take **HAXTOVAT** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual starting dose is 10 mg once a day. Your doctor may increase the dose, if necessary until you are taking the correct amount required. The maximum dose is 80 mg once a day. **HAXTOVAT** tablets can be taken at any time of the day with or without food. However, try to take your tablet at the same time every day. Remember to continue with your diet and lifestyle changes while you are taking **HAXTOVAT**.

Your doctor will tell you how long your treatment with HAXTOVAT will last. If you have the impression that the effect of HAXTOVAT is too strong or too weak, tell your doctor or pharmacist.

If you take more HAXTOVAT 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 take too many of these tablets you may experience some of the following symptoms – drowsiness, weakness, dizziness, tremor, coma, feeling sick, sweating, a blue colour to the skin and palpitations/rapid, irregular heartbeat.

If you forget to take HAXTOVAT

If you forget to take **HAXTOVAT**, take it as soon as you remember. Do not take a double dose to

make up for forgotten individual doses.

If you stop taking using HAXTOVAT

Do not stop taking **HAXTOVAT** until your doctor tells you to do so.

4. Possible side effects

HAXTOVAT can have side effects.

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

If any of the of the following happens, stop taking **[PRODUCTNAME]** 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 **[PRODUCTNAME]** and it can be life-threatening and lead to kidney problems.

- **HAXTOVAT** can cause serious muscle problems that can **lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are**

taking certain other medicines with HAXTOVAT (see Taking other medicines with **HAXTOVAT**).

- **Liver problems**

  Your doctor may do blood tests to check your liver before you start taking **HAXTOVAT** and if you have symptoms of liver problems while you take **HAXTOVAT**. Symptoms of liver problems include:

  - Feeling tired or weak.
  - Loss of appetite.
  - Upper belly pain.
  - Dark amber-coloured urine.
  - Yellowing of your skin or the whites of your eyes.

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

- Muscle problems like weakness, tenderness, cramps, spasms, stiffness or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual. This may be an early sign of a rare muscle problem.
- Muscle problems that do not go away even after your doctor has advised you to stop taking **HAXTOVAT**. Your doctor may do further tests to diagnose the cause of your muscle problems.
- Allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away.
- Nausea and vomiting.
- Passing brown or dark-coloured urine.
- Loss of appetite.

- You feel more tired than usual.
- Your skin and whites of your eyes get yellow.
- Stomach pain.
- Allergic skin reactions.

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

Frequent side effects:

Other side effects reported in clinical trials include the following:

Infection, headache, accidental injury, flu-like syndrome, back pain, constipation, diarrhoea, heartburn (dyspepsia), flatulence, sinus inflammation (sinusitis), sore throat (pharyngitis), rash, joint pain.

- 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.

Other frequent side effects which have been reported include the following:

Diarrhoea, constipation, wind, indigestion, headache, pain in joints, chest pain or tightness, cough or wheezing, difficulty breathing (dyspnea), weight loss or fever, trouble swallowing, sore throat, hoarseness, inability to sleep, back pain, numbness, tingling, reduced sensitivity to touch, dizziness and itching.

Other less frequent side effects which have been reported are:

Ringing in the ears, blurred vision, feeling unwell, loss of memory, impotence, loss of hair, and change in sense of taste, inflammation of the pancreas, inflammation of the liver, too few blood platelets, tendon problems, low blood sugar, high blood sugar, anorexia (eating disorder), weight gain, nerve disease affecting the extremities of the body.

Less frequently:

Swelling of hands and feet and muscle cramps.

Additional side effects reported after the marketing of **HAXTOVAT** include:

Frequency not known:

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

If you get side effects, talk to your doctor, ~~or~~ 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 or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of **HAXTOVAT**.

5. How to store HAXTOVAT

- Store all medicines out of reach of children
- Store at or below 25 °C
- Store in the original package
- Protect from light/ moisture
- Do not use after the expiry date stated on the label
- 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 HAXTOVAT contains

- The active substance is atorvastatin.

The other ingredients are:

- Microcrystalline Cellulose,
- Carbonate Carbonate
- Lactose Monohydrate
- Croscarmellose Sodium
- Hydroxypropyl Cellulose,
- Magnesium Stearate

What HAXTOVAT looks like and contents of the pack

HAXTOVAT 10 mg

90's Count HDPE Container

High Density Polyethylene Container 40 cc with 33 mm Neck (Heavy weight)

Pack size: 90 film coated tablets

1000's Count HDPE Container

High Density Polyethylene Container 250 cc with 53 mm Neck (Heavy weight)

with child resistant plastic caps with pulp liners 53 mm and a 2,0 g, Molecular sieve desiccant canister.

Pack size: 1000 film coated tablets

Blister pack 10 X10's Alu-Alu

Forming: Cold forming (60 microns PVC / 45 Microns Aluminium foil / 25 micro OPA), width 108 mm

Lidding Foil: 25 µ Plain aluminium foil (Hard Tempered) with 7 GSM HSL coating on bright side, width 108 mm

HAXTOVAT 20 mg

90's Count HDPE Container

HDPE container 60 cc with 33 mm neck (Heavy weight), with child resistant plastic caps with pulp liners 33 mm and Silica gel desiccant canister a 2,0 g,

Pack size: 90 film coated tablets

1000's Count HDPE Container

HDPE container 250 cc with 53 mm neck (Heavy weight), with child resistant plastic caps with pulp liners 53 mm and a 2,0 g, Molecular sieve desiccant canister.

Pack size: 1000 film coated tablets

Blister pack 10 X10's Alu-Alu

Forming Cold form foil (60 microns PVC / 45 microns Aluminium foil /25 microns OPA), width 139 mm

Lidding Foil: 25 µ Plain Aluminium foil (Hard Tempered) with 7 GSM HSL coating on bright side, width 139 mm

HAXTOVAT 40 mg

90's Count HDPE Container

HDPE container 120 cc with 38 mm neck (Heavy weight), with child resistant plastic caps with pulp liners 38 mm and Silica gel desiccant canister a 2,0 g,

Pack size: 90 film coated tablets

500's Count HDPE Container

HDPE container 500 cc with 53 mm neck (Heavy weight), with child resistant plastic caps with pulp liners 53 mm and a 2,0 g, Molecular sieve desiccant canister.

Pack size: 500 film coated tablets

Blister pack 10 X10's Alu-Alu

Forming Cold form foil (60 microns PVC / 45 microns Aluminium foil /25 microns OPA), width 139 mm

Lidding Foil: 25 µ Plain Aluminium foil (Hard Tempered) with 7 GSM HSL coating on bright side, width 139 mm

HAXTOVAT 80 mg

90's Count HDPE Container

HDPE container 200 cc with 38 mm neck (Heavy weight), with child resistant plastic caps with pulp liners 38 mm and Silica gel desiccant canister a 2,0 g,

Pack size: 90 film coated tablets

500's Count HDPE Container

HDPE container 950 cc with 53 mm neck (Heavy weight), with child resistant plastic caps with pulp liners 53 mm and a 2,0 g, Molecular sieve desiccant canister.

Pack size: 500 film coated tablets

Blister pack 10 X10's Alu-Alu

Forming Cold form foil (60 microns PVC / 45 microns Aluminium foil /25 microns OPA), width 148 mm

Lidding Foil: 25 µ Plain Aluminium foil (Hard Tempered) with 7 GSM HSL coating on bright side, width 148 mm

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate Campus

Building No. 2, First floor

74 Waterfall Drive

Midrand, 2066

Telephone: 012 644 1220

Fax number: 012 644 1564

e-mail address: nokuthula.n@heterodrugs.com

This leaflet was last revised in

14 JULY 2026

Registration number

HAXTOVAT 10: 57/7.5/0895

HAXTOVAT 20: 57/7.5/0896

HAXTOVAT 40: 57/7.5/0897

HAXTOVAT 80: 57/7.5/0898

Access to the corresponding Professional Information

Hetero Drugs South Africa (Pty) Ltd.,

Waterfall Corporate Campus,

Building 2, First Floor,

74 Waterfall Drive,

Midrand

2066