PATIENT INFORMATION LEAFLET

DYNATOR RANGE

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

DYNATOR 10 mg film coated tablet

DYNATOR 20 mg film coated tablet

DYNATOR 40 mg film coated tablet

DYNATOR 80 mg film coated tablet

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

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

DYNATOR 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.

1. WHAT DYNATOR CONTAINS:

The active substance is atorvastatin.

DYNATOR 10 mg: Each tablet contains atorvastatin calcium equivalent to 10 mg atorvastatin.

DYNATOR 20 mg: Each tablet contains atorvastatin calcium equivalent to 20 mg atorvastatin.

DYNATOR 40 mg: Each tablet contains atorvastatin calcium equivalent to 40 mg atorvastatin.

DYNATOR 80 mg: Each tablet contains atorvastatin calcium equivalent to 80 mg atorvastatin.

The other ingredients are crospovidone, magnesium stearate, microcrystalline cellulose, Opadry OYL – 28900 white, Sinespum C, sodium hydrogen carbonate, sodium lauryl sulphate.

Contains 0,02 % *w/w* butylhydroxyanisole, as a preservative.

Contains sugar.

DYNATOR 10 mg: 65,01 mg lactose monohydrate, 3,88 mg sucrose per tablet.

DYNATOR 20 mg: 130,02 mg lactose monohydrate, 7,77 mg sucrose per tablet.

DYNATOR 40 mg: 260,03 mg lactose monohydrate, 15,53 mg sucrose per tablet.

DYNATOR 80 mg: 520,05 mg lactose monohydrate, 31,07 mg sucrose per tablet.

2. WHAT DYNATOR IS USED FOR:

DYNATOR is used in adults:

- To lower the cholesterol in your blood. **DYNATOR** is prescribed if your cholesterol does not come down enough with exercise and a low-fat diet alone.
- For the prevention of heart disease in patients who are at an increased risk of heart disease such as smoking, high blood pressure, diabetes, low HDL-C (low levels of good cholesterol) or those with a family history of heart disease.
- For the prevention of incidents that may cause damage to the heart in patients who already have heart disease or high cholesterol.
- **DYNATOR** is also used in combination with other medicine to lower your cholesterol.

DYNATOR is used in children, 10 to 17 years of age to lower the cholesterol in your blood.

3. BEFORE YOU TAKE DYNATOR:

Do not take DYNATOR:

- If you are hypersensitive (allergic) to atorvastatin or to any of the other ingredients of **DYNATOR** (see **WHAT DYNATOR CONTAINS**).
- If you have an acute or chronic liver disease including cirrhosis.
- If you have had any unexplained abnormal blood tests for liver function.

- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding)**.
- If you are using rifampicin (to treat tuberculosis or TB), diltiazem (to treat heart rhythm disorders) or have a habit of consuming large amounts of grapefruit.
- If you have porphyria (a rare hereditary disease affecting the blood pigment with symptoms such as dark urine and extreme sensitivity of the skin to light).

Take special care with DYNATOR:

- If you have a history of liver disease, as **DYNATOR** may affect the enzyme levels in your liver.
- If you are taking large amounts of alcohol.
- If you have had repeated or unexplained muscle weakness, aches or pains (especially in the shoulders, thigh or lower back) or 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 '-statin' or 'fibrate' medicines).
- If your liver or kidney function is impaired.
- If you are suffering from a severe infection.
- If you have low blood pressure.
- If you are recovering from major surgery or trauma.
- If you have uncontrolled seizures (fits/convulsions).
- If you just had an organ transplant and are taking medicine to prevent transplant rejection.
- Before having any surgery (including dental surgery), tell your doctor or dentist in charge that you are taking **DYNATOR.**
- If you are taking medicines called protease inhibitors (used in the treatment of HIV and hepatitis) as these medicines may affect the way **DYNATOR** works.
- If you have had a previous stroke with bleeding into the brain, or have small pockets

of fluid in the brain from previous strokes, as high doses of **DYNATOR** (80 mg) may increase the risk of stroke.

- If you have a lung disorder, as **DYNATOR** may worsen these conditions (see **SIDE EFFECTS**).
- If you have diabetes or at risk of developing diabetes, as your doctor may increase the frequency of your blood sugar monitoring.
- If you take an antibiotic eyedrop or use a cream containing fusidic acid.

Your doctor may request tests to monitor your condition before and/or during treatment.

Taking DYNATOR with food and drink:

Drinking too much alcohol may change the way **DYNATOR** affects your body. You should not drink alcoholic beverages on a daily basis or take more than 1 or 2 drinks at any time. Before prescribing medicines to lower your cholesterol, your doctor will probably try to control your cholesterol by prescribing a personal diet for you. Such a diet will be lower in total fat, particularly saturated fat, and dietary cholesterol. **DYNATOR** will only be effective when a scheduled diet is properly followed.
Do not take grapefruit juice while taking **DYNATOR**, as this will result in higher levels of **DYNATOR** in your blood.
DYNATOR can be taken with or without meals.

Pregnancy and breastfeeding:

Do not take **DYNATOR** if you are pregnant, planning to become pregnant or breastfeeding. Whilst taking **DYNATOR** you need to ensure that you use adequate contraception and do not fall pregnant,
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using **DYNATOR**.

If you are planning pregnancy, you need to allow at least one month to pass after having stopped **DYNATOR** treatment.

Driving and using machinery:

Do not operate machinery or drive a vehicle until you know how **DYNATOR** affects you, as these tablets may cause nausea, headache and dizziness.

Important information about some of the ingredients of DYNATOR:

DYNATOR contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **DYNATOR**.

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

DYNATOR contains lactose and sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with DYNATOR:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

DYNATOR may interact with the following medicines:

- Rifampicin (used to treat TB) may affect the way **DYNATOR** works.
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem may affect the way **DYNATOR** works and your condition will need to be monitored.
- Ciclosporin (medicine used after organ transplant) or delavirdine (an anti-retroviral medicine).

Your dose of **DYNATOR** may need to be reduced and your condition monitored.

- Itraconazole, ketoconazole, fluconazole, voriconazole, clotrimazole or posaconazole (antifungal treatment). Your dose of **DYNATOR** may need to be reduced and your condition monitored.
- Erythromycin, telithromycin and clarithromycin (antibiotics) may increase the effects of **DYNATOR**.
- Medicines used in the treatment of HIV (such as indinavir, ritonavir, lopinavir, atazanavir, darunavir, saquinavir, tipranavir, efavirenz or combination treatment of these medicines) may affect the way **DYNATOR** works.
- Niacin (Vitamin B3) used to treat high cholesterol may increase the risk of muscular side effects (see **SIDE EFFECTS**).
- Other medicines used to reduce cholesterol levels (such as gemfibrozil, other fibrates, colestipol, ezetimibe) may increase the risk of unwanted skeletal and muscular side effects (see **SIDE EFFECTS**).
- Fusidic acid (an antibiotic) as taking **DYNATOR** at the same time is not recommended and treatment with **DYNATOR** may need to be stopped (see **Take special care with DYNATOR**).
- Medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone, ranolazine may affect the way **DYNATOR** works and your condition will need to be monitored.
- Cimetidine (used for heartburn or stomach ulcers) has no effect on **DYNATOR**.
- Antacids (indigestion products containing aluminium or magnesium) may affect the way **DYNATOR** works.
- Warfarin (medicine that prevents the blood from forming clots) as your doctor will want to monitor your condition.
- Cholestyramine (medicine to treat high cholesterol or diarrhoea).
- Oral contraceptives, as **DYNATOR** may reduce the effects of some contraceptive tablets.

- Other medicines known to interact with **DYNATOR** include stiripentol (an anticonvulsant for epilepsy), phenazone (a painkiller), colchicine (used to treat gout), boceprevir or telaprevir (used to treat liver disease such as hepatitis C), nefazondone or St John's Wort (medicines used for depression), and dose adjustments or careful monitoring may be required.

4. HOW TO TAKE DYNATOR:

Do not share medicines prescribed for you with any other person. Always take **DYNATOR** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The dosage will be different for different patients.
DYNATOR can be taken with or without meals.
Before starting treatment, your doctor will place you on a low-cholesterol diet, which you should maintain during therapy with **DYNATOR**.

Adult dose:

The usual starting dose is 10 mg at any time of the day with or without food.
Your doctor may increase your dosage to a maximum of 80 mg daily at intervals of 4 weeks. The dosage will depend on your condition and your response to the treatment.

Children (10-17 years of age):

The usual starting dose is 10 mg at any time of the day.
Your doctor may increase your dosage to a maximum of 20 mg daily at intervals of at least 4 weeks.

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

If you take more DYNATOR than you should:

In the event of an overdose, consult your doctor or pharmacist immediately. 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 a dose of DYNATOR:

If you miss a dose, take it as soon as you remember. Do not take **DYNATOR** if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with DYNATOR is stopped:

It is important that you continue the course of treatment. Do not stop taking **DYNATOR** unless your doctor tells you to do so.

5. POSSIBLE SIDE EFFECTS:

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

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

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DYNATOR**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Severe pain in the upper abdomen or back, nausea and vomiting as this may be a sign of gallstones or a condition called pancreatitis.
- Muscle weakness, tenderness or pain, or difficulty moving your arms or legs and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown.
- Low blood pressure (feeling dizzy), chest pain, irregular or fast heartbeat.
- Bruising easily (thrombocytopenia).
- Weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis).
- Hepatitis (swelling and inflammation of the liver, characterised by symptoms such as, abdominal pain or distension, dark urine and pale or clay-coloured stools, fatigue, fever, general itching, loss of appetite, nausea and vomiting) and jaundice (yellow discolouration of the skin and eyes).
- Memory loss, mood changes, inability to make decisions or to concentrate.
- Stevens-Johnson syndrome (a life threatening skin disorder with symptoms such as a red-purplish rash and blisters).
- Swelling in any part of the body.
- Changes in kidney function and passing of urine, including the amount, frequency and colour of the urine, blood in the urine.

- Fainting (syncope).
- Low blood sugar (hypoglycaemia), high blood sugar (hyperglycaemia).
- Facial paralysis, increased infections.

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:

- Sleeplessness.
- Sinusitis, sore throat, nose bleeds.
- Headache.
- Pain or inflammation in the large and small joints or shoulder, bone pain, tendon pain or swelling, tendon rupture, neck stiffness and pain.

Less frequent side effects:

- Nightmares.
- Diarrhoea, constipation, flatulence (wind).
- Weight gain, anorexia, increased appetite.
- Blurred vision.
- Ringing in the ears (tinnitus), deafness.
- Skin rashes or other skin conditions, such as flushing, hives, itching, dry skin, eczema, acne and hair-loss, to serious skin conditions causing blisters and peeling, tissue damage.
- Enlarged breasts in men.
- Flu-like symptoms (chills, difficult breathing, dizziness, fever, headache, muscle and bone pain, fatigue and shivering), abnormal physical weakness, lack of energy.

Side effects with unknown frequency:

- Anaemia, swelling of the lymph glands.
- Peripheral neuropathy (damage to nerves outside the spinal cord, affecting the normal functioning of the body's organs and movement and/or feeling of sensation in the extremities, including your arms and legs).
- Muscle cramps, gout, arthritis.
- Depression, drowsiness.
- Nausea, vomiting, abdominal pain, heartburn, black tarry stools.
- Asthma, bronchitis, shortness of breath, chest infection, throat infection, nasal congestion.
- Tingling sensation in hands, feet or lips (pins and needles).
- Reduced sense of touch or sensation (numbness).
- Migraine, dizziness, taste loss, taste disturbances.
- Lazy eye, dry eyes, vision disturbances, glaucoma (increased pressure in the eye causing gradual loss of sight), bleeding in the eye.
- Sensitivity of the skin to sunlight (photosensitivity).
- Lumps in the breast, abnormal menstrual bleeding.
- Problems with sexual performance.
- Fatigue, fever, general feeling of discomfort or being unwell.
- Accidental injury.

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

6. STORING AND DISPOSING OF DYNATOR:

Store at or below 25 °C.

Protect from light and moisture.

Keep the blisters in the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the label or container.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF DYNATOR:

DYNATOR tablets are packed into silver, hard aluminium / aluminium blister strips of 3 x 10 tablets inside an outer cardboard box.

8. IDENTIFICATION OF DYNATOR:

DYNATOR 10 mg:

Cylindrical, biconvex, coated white tablet, scored on one side and with the code, AT1 on the other side.

DYNATOR 20 mg:

Cylindrical, biconvex, coated white tablet, scored on one side and with the code, AT2 on the other side.

DYNATOR 40 mg:

Cylindrical, biconvex, coated white tablet, scored on one side and with the code, AT4 on the other side.

DYNATOR 80 mg:

Oblong, biconvex, coated white tablets, scored on one side and with the code, AT 8 on the other.

9. REGISTRATION NUMBERS:

DYNATOR 10 mg: A43/7.5/0167

DYNATOR 20 mg: A43/7.5/0168

DYNATOR 40 mg: A43/7.5/0169

DYNATOR 80 mg: A43/7.5/0170

Namibia
DYNATOR 10 mg: NAM NS2 13/7.5/0111
DYNATOR 20 mg: NAM NS2 13/7.5/0112
DYNATOR 40 mg: NAM NS2 13/7.5/0113
DYNATOR 80 mg: NAM NS2 13/7.5/0114

10. NAME, BUSINESS, ADDRESS AND TELEPHONE NUMBER OF THE REGISTRATION HOLDER:

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