PATIENT INFORMATION LEAFLET

DYNATOR PLUS RANGE

SCHEDULING STATUS:

S4

DYNATOR PLUS 10/10 mg film coated tablet

DYNATOR PLUS 10/20 mg film coated tablet

DYNATOR PLUS 10/40 mg film coated tablet

DYNATOR PLUS 10/80 mg film coated tablet

Ezetimibe and Atorvastatin

DYNATOR PLUS contains sugar (lactose monohydrate and lactose anhydrous) in the following quantities: DYNATOR PLUS 10/10 MG (171,15 mg; 13,7 mg), DYNATOR PLUS 10/20 mg (171,15 mg; 27,4 mg), DYNATOR PLUS 10/40 mg (171,15 mg; 54,8 mg), DYNATOR PLUS 10/80 mg (171,15 mg, 109,6 mg).

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

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

PATIENT INFORMATION LEAFLET

DYNATOR PLUS RANGE

1. What DYNATOR PLUS is and what it is used for

DYNATOR PLUS contains ezetimibe and atorvastatin.

DYNATOR PLUS is used

- as a cholesterol-lowering medicine
- in patients whose cholesterol levels are too high and when diet alone cannot lower these levels adequately
- to reduce elevated total-cholesterol and LDL (bad) cholesterol in the blood

High cholesterol can be treated in two main ways:

Lifestyle Changes – including a cholesterol-lowering diet, increased physical activity, and weight management.

Medication – Cholesterol-lowering medicines are used together with lifestyle changes to help lower cholesterol. Your doctor has prescribed DYNATOR PLUS to help lower your cholesterol.

2. What you need to know before you take DYNATOR PLUS

Do not take DYNATOR PLUS:

- if you are hypersensitive (allergic) to ezetimibe or atorvastatin or any of the other ingredients of DYNATOR PLUS (see section 6)
- if you have or had a disease that affects the liver
- if you had any unexplained abnormal blood tests for liver function
- if you are pregnant, trying to become pregnant or are breast-feeding
- if you are taking medicine called rifampicin (used to treat tuberculosis) and diltiazem (used to treat high blood pressure) with grapefruit juice (see section DYNATOR PLUS with food drink and alcohol).

Warnings and precautions

Special care should be taken with DYNATOR PLUS:

- if you drink a lot of alcohol and have a history of liver disease
- if you have unexplained muscle pain, tenderness or weakness, especially if it is accompanied by a general feeling of discomfort, illness and fatigue. Your doctor will do some blood tests as you may be suffering from a condition called myopathy (muscle tissue disease)
- if you have symptoms like muscle pain, muscle weakness and dark red or brown urine or decreased urination. You may have a condition called rhabdomyolysis which is a breakdown of muscle fibres
- if you take the following medicine: ciclosporin (used to prevent organ rejection), fibric acid derivatives (lipid lowering medicine), Vitamin B3, antibiotic medicine called erythromycin and colchicine (to treat gout), medicine used to treat liver infection called telaprevir, boceprevir, antiretroviral medicine (used to treat HIV/AIDS infections) combinations called saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, and fosamprenavir plus ritonavir – as these can lead to a condition called myopathy (muscle tissue disease)
- if you are taking a medicine called fusidic acid (antibiotic often used in topical creams and eyedrops) – as these can lead to muscle related side effects
- if you had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- if you have risk factors which can lead kidney problems i.e. low blood pressure, major surgery, trauma, uncontrolled fits/seizures
- if you have gallstones and are also treated with the medicine called fenofibrate (medicine used to lower cholesterol levels)

- if you are taking medicine used to treat blood clots (i.e. warfarin)
- if you develop a tight chest, dry cough, feel tired, experience weight loss and fever, notify your doctor immediately
- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

Other medicines and DYNATOR PLUS

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

There are some medicines that may change the effect of DYNATOR PLUS or their effect may be changed by DYNATOR PLUS if taken together with DYNATOR PLUS. These include

- medicines used to alter the way your immune system works (ciclosporin), other cholesterol lowering medicine called fibric acid derivatives, niacin (vitamin B3) or certain antibiotics (i.e. erythromycin, daptomycin) or antifungal medicines (i.e. clotrimazole), may lead to a condition called myopathy (pain or weakness in the muscles)
- medicines used to treat tuberculosis and HIV infection e.g. efavirenz and rifampicin as the effect of DYNATOR PLUS may be less
- antacids (indigestion medicine containing aluminium or magnesium)
- cholestyramine and colestipol (medicines used to lower cholesterol) as the effect of DYNATOR PLUS may be less
- fibrates e.g. fenofibrate or gemfibrozil (medicine used to lower cholesterol)
- ciclosporin (medicine often used in organ transplant patients to prevent organ transplant rejection) as it can increase the amount of atorvastatin, as in DYNATOR PLUS, in your blood

- erythromycin/clarithromycin (antibiotics used to treat infections) as it can increase the amount of atorvastatin, as in DYNATOR PLUS, in your blood
- medicines used in the treatment of HIV e.g. ritonavir, saquinavir, lopinavir; and medicine used to treat liver infection e.g. telaprevir, boceprevir as it can increase the amount of atorvastatin, as in DYNATOR PLUS, in your blood
- medicines to treat breast cancer, e.g. elbasvir and grazoprevir, the dosage of DYNATOR PLUS may be changed by your doctor
- medicines used for chest pain or high blood pressure, e.g. diltiazem as it can increase the amount of atorvastatin, as in DYNATOR PLUS, in your blood
- antifungal medicine called itraconazole as it can increase the amount of atorvastatin, as in DYNATOR PLUS, in your blood
- medicines to regulate your heart rhythm e.g. digoxin as it may lead to higher levels of digoxin in your blood
- oral contraceptives (the “pill”) as it can influence the effect of the “pill”
- anticoagulants (medicine used to treat blood clotting issues) e.g. warfarin as it can have an effect how long it takes blood to form a clot
- medicine used to treat gout called colchicine as it can lead to a condition called myopathy (weakness or pain in the muscles)
- medicine containing fusidic acid (antibiotic used to treat infections) (see section 4.3) as it can lead to severe muscle problems including a condition called rhabdomyolysis (abnormal muscle breakdown which can lead to kidney problems).

DYNATOR PLUS with food, drink and alcohol

DYNATOR PLUS is for oral administration and can be administered at any time of the day, with or without food.

Grapefruit juice

Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of DYNATOR PLUS.

Alcohol

Avoid drinking too much alcohol while taking this medicine (see section 2).

Pregnancy, breastfeeding and fertility

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 healthcare professional for advice before using DYNATOR PLUS.

Do not take DYNATOR PLUS if you are able to become pregnant unless you use reliable contraceptive measures.

If you are pregnant or plan to become pregnant, you should not use DYNATOR PLUS.

You should not breastfeed while using DYNATOR PLUS.

The impact of DYNATOR PLUS on a woman's fertility is unknown since no studies have been conducted.

Driving and using machines

DYNATOR PLUS is not expected to interfere with your ability to drive or use machines. However, it is not always possible to predict to what extent DYNATOR PLUS may interfere with your daily activities. You may experience dizziness. You should ensure that you do not engage in the above activities until you are aware of the measure to which DYNATOR PLUS affects you.

DYNATOR PLUS contains lactose

If you have told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take DYNATOR PLUS

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

Always use DYNATOR PLUS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

You should be on a (lipid) fat-lowering diet and weight loss programme and continue this diet during treatment with DYNATOR PLUS.

Adults

The usual starting dose is 10/10 mg once a day – swallowed whole and can be taken with or without food. Depending on your response to treatment, your doctor may adjust your dose to a higher strength after 4 weeks.

If your doctor has prescribed DYNATOR PLUS together with cholestyramine (a bile acid sequestrant used for lowering LDL cholesterol in conjunction with diet modification) or any other bile acid sequestrant, DYNATOR PLUS should be taken at least 2 hours before or 4 hours after taking the bile acid sequestrant.

Your doctor will tell you how long your treatment with DYNATOR PLUS will last. Do not stop treatment early because your cholesterol levels will change again.

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

If you take more DYNATOR PLUS 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 DYNATOR PLUS

If you forget to take DYNATOR PLUS, take a dose as soon as you remember, then continue to take DYNATOR PLUS at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DYNATOR PLUS

Talk to your doctor or pharmacist because your cholesterol may rise again.

4. Possible side effects

DYNATOR PLUS can have side effects.

Not all side effects reported for DYNATOR PLUS are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DYNATOR PLUS, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using DYNATOR PLUS 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.

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

- changes in the way your heart beats, for example, if you notice it is beating slower than normal
- Stevens-Johnson syndrome (serious skin disorder that begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, usually due to a reaction to medication) or other serious skin disorder
- muscle weakness, tenderness, pain or rupture 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)
- yellowing of the skin, jaundice, liver failure
- shortness of breath.

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:

- difficulty in sleeping
- reduced sense of touch or sensation, pins-and-needles, dizziness, headache
- nausea (feeling sick), diarrhoea (loose watery stools), abdominal pain, indigestion, constipation, flatulence
- blood test results that show your liver function is abnormal
- itching, rash
- muscle pain, joint pain, back pain, myalgia (weakness or pain in the muscles)
- fatigue (extreme tiredness), physical weakness, lack of energy, chest pain.

Less frequent side effects:

- viral infections, sinus infection, sore throat, upper respiratory tract infection, the “flu”, coughing, infection of the main airways of the lungs (symptoms include coughing, sore throat and wheezing)
- reduction in blood platelets, which increases risk of bleeding or bruising
- hypoglycaemia (lower than normal blood sugar), hyperglycaemia (high blood sugar), weight gain, lack of appetite
- damage to the nerves which can cause numbness, pain and weakness, memory loss, altered taste
- ringing in the ears
- vomiting (being sick), inflammation of the pancreas causing pain in the upper abdomen
- inflammation of the liver
- hair loss, large, fluid-filled blisters, a rash of round, red welts on the skin that itch intensely, bulging rash-like (bull’s-eye shaped) lesions of the skin, acne, hives
- inflammation in the muscles, muscle cramps, muscle fatigue, pain in extremities, muscle spasms, stiffness in bones and muscles, back pain
- impotence (men unable to achieve an erection)
- general feeling of discomfort, illness, or unease, dizziness
- tendon rupture and accidental injury
- low potassium levels as detected by blood tests (symptoms include weakness, fatigue, muscle cramps or twitching)
- depression, sleep disorder
- hot flushes
- increased liver enzymes as detected by blood tests

The following side effects have been reported but the frequency for them to occur is not known:

- gallstones and inflammation of the gallbladder wall (symptoms include fever, and pain and tenderness in the right upper abdominal area, bloating, little or no appetite, nausea, vomiting)
- memory loss, forgetfulness, memory impairment, confusion
- muscle weakness, difficulty in lifting arms over the head and climbing stairs and as a result of an autoimmune disease called immune-mediated necrotizing myopathy
- common cold, bladder infection
- an eating disorder characterized by an abnormally low body weight, high or low blood sugar levels
- nightmares
- blurred vision, deafness
- high blood pressure
- nosebleed, asthma (a condition in which your airways narrow and swell and may produce extra mucus. This can make breathing difficult and trigger coughing, a whistling sound (wheezing) when you breathe out and shortness of breath)
- acid reflux, burping/belching, dry mouth
- intense itching, dark urine and light-coloured bowel movements due to a condition called cholestasis
- breast development in males
- fever
- white blood cells as detected in urine tests.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product. By reporting side effects, you can help provide more information on the safety of DYNATOR PLUS.

5. How to store DYNATOR PLUS

Store all medicines out of reach of children.

Store at or below 25˚C in the original package.

Do not use after the expiry date stated on the carton.

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 DYNATOR PLUS contains

The active substances are atorvastatin and ezetimibe.

DYNATOR PLUS10/10 mg : Each film coated tablet contains 10 mg ezetimibe and atorvastatin calcium trihydrate equivalent to 10 mg atorvastatin.

DYNATOR PLUS10/20 mg : Each film coated tablet contains 10 mg ezetimibe and atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin.

DYNATOR PLUS10/40 mg : Each film coated tablet contains 10 mg ezetimibe and atorvastatin calcium trihydrate equivalent to 40 mg atorvastatin.

DYNATOR PLUS10/80 mg : Each film coated tablet contains 10 mg ezetimibe and atorvastatin calcium trihydrate equivalent to 80 mg atorvastatin.

DYNATOR PLUS contains sugar (lactose monohydrate and lactose anhydrous) in the following quantities: DYNATOR PLUS 10/10 mg (171,15 mg; 13,7 mg), DYNATOR PLUS 10/20 mg (171,15 mg; 27,4 mg), DYNATOR PLUS 10/40 mg (171,15 mg; 54,8 mg) and DYNATOR PLUS 10/80 mg (171,15 mg; 109,6 mg).

The other ingredients are:

Tablet cores:

Calcium carbonate, colloidal anhydrous silica, crospovidone, hydroxy propyl cellulose, lactose anhydrous, lactose monohydrate, microcrystalline cellulose, povidone, sodium lauryl sulphate, sodium stearyl fumarate.

Coating:

Opadry White AMB, lecithin, polyvinyl alcohol, talc, titanium dioxide, xanthan gum

What DYNATOR PLUS looks like and contents of the pack

DYNATOR PLUS10/10 mg *:* White to off-white capsule-shaped, biconvex, film coated tablet debossed with 'AE' on one side and 1 on the other side.

DYNATOR PLUS 10/20 mg: White to off-white capsule-shaped, biconvex, film coated tablet debossed with 'AE' on one side and '2' on the other side.

DYNATOR PLUS 10/40 mg : White to off-white capsule-shaped, biconvex, film coated tablet debossed with 'AE' on one side and '3' on the other side.

DYNATOR PLUS 10/80 mg : White to off-white capsule-shaped, biconvex, film coated tablet debossed with 'AE' on one side and ' ' on the other side

30's pack: 3 x Cold form Alu/Alu: Laminated Aluminium foil, one side bright and shinning, the other side relatively dull for cold forming blister pack., 10 tablets per blister, enclosed in a carton box.

Holder of Certificate of Registration

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