1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

DUCETIM PLUS 10/10 tablets

Ezetimibe/Simvastatin

Contains sugar: Lactose monohydrate 60,42 mg and lactose anhydrous 6,84 mg

DUCETIM PLUS 10/20 tablets

Ezetimibe/Simvastatin

Contains sugar: Lactose monohydrate 81,82 mg and lactose anhydrous 62,68 mg

DUCETIM PLUS 10/40 tablets

Ezetimibe/Simvastatin

Contains sugar: Lactose monohydrate 124,63 mg and lactose anhydrous 174,37 mg

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DUCETIM 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 DUCETIM PLUS is and what it is used for

DUCETIM PLUS contains the active substances ezetimibe and simvastatin. DUCETIM PLUS is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol), and fatty substances called triglycerides in the blood. In addition, DUCETIM PLUS raises levels of “good” cholesterol (HDL cholesterol).

DUCETIM PLUS is used for patients who cannot control their cholesterol levels by diet alone. You should stay on a cholesterol-lowering diet while taking this medicine.

DUCETIM PLUS is used in addition to your cholesterol-lowering diet if you have:

• a raised cholesterol level in your blood (primary hypercholesterolaemia [heterozygous familial and non-familial]) or elevated fat levels in your blood (mixed hyperlipidaemia):

• that is not well controlled with a statin alone,

• for which you have used a statin and ezetimibe as separate tablets.

• a hereditary illness (homozygous familial hypercholesterolaemia) that increases the cholesterol level in your blood.

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

Do not take DUCETIM PLUS:

- If you are hypersensitive (allergic) to ezetimibe, simvastatin, any other ‘statin’ or any of the other ingredients of DUCETIM PLUS (listed in section 6).

- If you suffer from liver disease.
- If you are pregnant or breastfeeding your baby.
- If you are a child.
- If you take itraconazole, ketoconazole (medicines used to treat fungal infections).
- If you take erythromycin, clarithromycin, telithromycin or fusidic acid (antibiotics used to treat bacterial infections).
- If you take HIV protease inhibitors such as lopinavir, ritonavir or darunavir (medicines used to treat HIV Infection).
- If you take a lomitapide or a fibrate such as gemfibrozil (medicines used to treat high cholesterol).
- If you take ciclosporin (a medicine used to prevent organ rejection in patients who had an organ transplant.
- If you take danazol (a medicine used to treat certain conditions of the uterus and breasts).
- If you take nefazodone (a medicine used to treat depression).

Warnings and precautions

Take special care with DUCETIM PLUS:

- If you experience muscle pain, tenderness or weakness. You must contact your doctor immediately as these may be signs of myopathy (a muscle disease).
- Especially if you:

  - are a female patient;

  - are an elderly patient (age ≥ 65 years);

  - have kidney problems;

  - have uncontrolled underactive thyroid disease;

  - have a family history of muscle disorders;

- have a history of muscle toxicity when taking statins (medicines to treat high cholesterol);

- abuse alcohol.

- If you experience a raise in your blood sugar levels.
- If you experience difficulty in breathing, non-productive cough, fatigue, weight loss and fever as these may be symptoms of a lung condition causing scarring of the lungs.
- If you take certain medicines as these may increase your risk to develop muscle pain or muscle injury:

  - Diltiazem, used to treat certain heart conditions.

  - Daptomycin, used to treat bacterial infections.

  - Fibrates, used for the lowering of cholesterol.
- If you take medicine to prevent your blood from clotting e.g. warfarin.

Children

Safety and efficacy have not been demonstrated.

Other medicines and DUCETIM PLUS

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

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

- Niacin (nicotinic acid), fibrates and colestyramine, medicines used to treat high cholesterol.
- Amiodarone, verapamil, diltiazem, medicines used to treat certain heart conditions.
- Amlodipine, a medicine used to treat high blood pressure.

- Fusidic acid, an antibiotic used to treat bacterial infections.
- Antacids such as magnesium hydroxide, aluminium hydroxide used to treat indigestion.
- Anticoagulants such as warfarin, medicines used to prevent your blood from clotting.
- Elbasvir, grazoprevir used to treat Hepatitis C (a liver condition).
- Rifampicin, used to treat tuberculosis (TB).
- Colchicine, used to treat gout.

DUCETIM PLUS with food

DUCETIM PLUS should be taken as a single daily dose in the evening, with or without food.

Intake of grapefruit juice during treatment with DUCETIM PLUS should be avoided.

Pregnancy, breastfeeding and fertility

You should not take DUCETIM PLUS if you are pregnant or breastfeeding your baby.

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 provider for advice before taking this medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. However, when driving vehicles or operating machines, it should be taken into account that dizziness has been reported and therefore you should exercise caution.

You should ensure that you do not engage in the above activities until you are aware of the measure to which DUCETIM PLUS affects you (see section 4).

DUCETIM PLUS contains lactose

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

3. How to take DUCETIM PLUS

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

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

Your doctor will place you on a standard cholesterol-lowering diet before prescribing DUCETIM PLUS to you. You should continue on this diet during treatment with DUCETIM PLUS.

Your doctor will individualise your dose based on the level of cholesterol in your blood.

The usual dose for DUCETIM PLUS is a single daily dose in the evening, with or without food.

Your doctor will tell you how long your treatment with DUCETIM PLUS will last.

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

If you take more DUCETIM 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 DUCETIM PLUS

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

4. Possible side effects

DUCETIM PLUS can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and 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 reaction to DUCETIM 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:

- If you bruise excessively, see superficial bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots (petechiae), usually on the lower legs, experience prolonged bleeding from cuts, these may be symptoms of a low platelet count (thrombocytopenia).
- If your skin is pale, you are tired and weak and feel out of breath, these may be symptoms of a low red blood cell count (anaemia).

- If you feel tired, have flu-like symptoms, have dark urine, have a pale stool, experience abdominal pain, weight loss and loss of appetite, yellowing of the skin and eyes, these may be symptoms of liver problems.
- If you have fever, increased heart rate, nausea, vomiting and feel a pain in the upper part of your belly, these may be signs of inflammation of your pancreas (pancreatitis).
- Unexplained muscle pain, tenderness or weakness, particularly if accompanied by a general feeling of unwellness or fever (myopathy/rhabdomyolysis).

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:

- Headache,
- winds, stomach pain, diarrhoea,
- increased liver enzymes as indicated on laboratory results,
- fatigue and muscle pains.

Less frequent side effects:

- Depression, sleeplessness,
- dizziness, ‘pins-and-needles’ in extremities, impaired memory,
- nausea, constipation, dyspepsia, vomiting,
- general feeling of discomfort (malaise),
- swelling of the arms/legs due to water retention,
- weight loss,
- abnormal laboratory results (bilirubin/ blood uric acid/ liver enzymes/ protein in urine/clotting factors),
- joint pain, muscle cramps.

Side effects with an unknown frequency

- Lack of energy (asthenia).

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. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of DUCETIM PLUS.

5. How to store DUCETIM PLUS

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blisters enclosed in carton until required for use.

Do not store in a bathroom.

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 DUCETIM PLUS contains

Each DUCETIM PLUS 10/10 tablet contains 10 mg ezetimibe and 10 mg simvastatin.

Each DUCETIM PLUS 10/20 tablet contains 10 mg ezetimibe and 20 mg simvastatin.

Each DUCETIM PLUS 10/40 tablet contains 10 mg ezetimibe and 40 mg simvastatin.

The other ingredients are butylhydroxytoluene, croscarmellose sodium, hypromellose, lactose anhydrous, lactose monohydrate and sodium stearyl fumarate.

What DUCETIM PLUS looks like and contents of the pack

DUCETIM PLUS 10/10 is a white, oblong tablet, with 8,0 mm ± 0,2 mm length and 4,4 mm ± 0,2 mm width.

DUCETIM PLUS 10/20 is a white, oblong tablet scored on one side, with 10,0 mm ± 0,2 mm length and 5,5 mm ± 0,2 mm width.

DUCETIM PLUS 10/40 is a white, oblong tablet, with 14,8 mm ± 0,2 mm length and 6,0 mm ± 0,2 mm width.

Tablets are packed in white 254 µm polyvinylchloride/70 µm polyethylene, ethylene vinyl alcohol, polyethylene/102 µm clear, poly-chloro-tri-fluro-ethylene film sealed with Aluminium 20 µm with 10 tablets per blister strip. The blister strips are then packed into a cardboard carton containing 30 tablets per pack.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead

2191

Hotline: 0800 122 912

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30 August 2022

Registration number

DUCETIM PLUS 10/10: 54/7.5/0690

DUCETIM PLUS 10/20: 54/7.5/0691

DUCETIM PLUS 10/40: 54/7.5/0692

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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