Applicant: Abbott Laboratories S.A (Pty) Ltd
Product name: Lypstaplus
Dosage form & **strength:** 10 mg rosuvastatin/10 mg ezetimibe film-coated tablets & 20 mg rosuvastatin /10 mg ezetimibe film-coated tablets

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

Lypstaplus 10 mg/ 10 mg film-coated tablets

Lypstaplus 20 mg/ 10 mg film-coated tablets

Rosuvastatin and ezetimibe

Contains sugar: Mannitol (152,53 mg)

Read all of this leaflet carefully before you start taking Lypstaplus

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

1. What Lypstaplus is and what it is used for

Lypstaplus contains the active medicines rosuvastatin and ezetimibe.

Lypstaplus helps to lower cholesterol levels. It is used in people whose cholesterol levels are too high and when diet alone cannot lower these levels adequately.

What is high cholesterol

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of low density lipoprotein (LDL) and high density lipoprotein (HDL) cholesterol.
LDL cholesterol is often called "bad" cholesterol because it can build up in the walls of your arteries forming plaque. Eventually this plaque build-up can lead to a narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain. This blocking of blood flow can result in a heart attack or stroke.
HDL cholesterol is often called "good" cholesterol because it helps keep the bad cholesterol from building up in the arteries and protects against heart disease.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. By lowering your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.
Your doctor *may* prescribe Lypstaplus if you are already taking both rosuvastatin and ezetimibe at the same dose level.
This medicine does not help you lose weight.

2. What you need to know before you take Lypstaplus

Do not take Lypstaplus if you

- are allergic to rosuvastatin, ezetimibe or any of the other ingredients of this medicine (listed in section 6).
- have liver conditions or active liver disease.
- have severe kidney disease.
- have repeated, unexplained muscle aches or pains (myopathy) or have a previous history of muscular problems from using other medicines used to treat high cholesterol.
- take a medicine called to suppress your immune system, ciclosporin (used for example, after organ transplants).
- are pregnant or intend to become pregnant. If you are a woman of childbearing age and are taking Lypstaplus, use a proven method of birt control to avoid pregnancy.
- The medicine may affect your developing baby if you take it during pregnancy (see Pregnancy,

breastfeeding and fertility).

- are breastfeeding, Lypstaplus may pass into breast milk and affect your baby (see Pregnancy, breastfeeding and fertility).
- have gall bladder disease and you are taking another medicine to lower cholesterol levels, called fenofibrate (see Other medicines and Lypstaplus).
- are taking an antibiotic medicine to treat infection, called fusidic acid (see Other medicines and Lypstaplus).
- Lypstaplus is not recommended for use in children (see Warnings and precautions).
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Lypstaplus or other related medicines.

If any of the above applies to you (or you are in doubt), please contact your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lypstaplus if you:

- have problems with your kidneys.
- have kidney impairment, as you may be at risk to develop muscle weakness (myopathy).
- have problems with your liver. Your doctor may ask you to have your liver function tested before you start to take Lypstaplus.
- have had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever. Also tell your doctor or pharmacist if you have a muscle weakness that is constant.
- have been diagnosed with high blood glucose levels.
- are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian). Your doctor needs to choose the right dose to suit you.
- take medicines used to fight infections, including HIV or hepatitis C infection e.g. lopinavir/ritonavir and/or atazanavir or simeprevir, please see "Other medicines and Lypstaplus".

- have short breath, difficulty breathing, cough and worsening of your health, tell your doctor. You may have a lung condition called interstitial lung disease.
- regularly drink large amounts of alcohol.
- notice any disturbances in your sleep, as Lypstaplus may affect your sleep.
- take other medicines called fibrates to lower your cholesterol. Please see "Other medicines and Lypstaplus".
- have low thyroid hormone levels (hypothyroidism), as you may be at risk to develop muscle weakness (myopathy).
- are elderly, as you may be at risk to develop muscle weakness (myopathy).
- are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Lypstaplus can lead to serious muscle problems (rhabdomyolysis).
- If you are taking a medicine to suppress your immune system, called ciclosporin (See 'other medicines and Lypstaplus')
- If any of the above applies to you (or if you are not sure): check with your doctor or pharmacist before you actually start taking any dose of Lypstaplus.
- In a small number of people, statins can affect the liver. This is identified by a simple test which looks for increased levels of liver enzymes in the blood. For this reason, your doctor will regularly carry out this blood test (liver function test) during treatment with this medicine. It is important to go to the doctor for the prescribed laboratory checks.
- While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.
- If you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) asstatins may sometimes aggravate the condition or lead to the occurrence of myasthenia (see section 4).

If any of the above applies to you (or if you are not sure): check with your doctor or pharmacist before

you actually start taking any dose of this medicine.

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Lypstaplus treatment. Stop using Lypstaplus and seek medical attention immediately if you notice any of the symptoms described in section 4.

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

Children and adolescents

The use of this medicine is not recommended in children and adolescents under the age of 18 years (see Do not take Lypstaplus).

Other medicines and Lypstaplus

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

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

- Ciclosporin: medicine used to suppress the immune system (used for example, after organ transplants to prevent rejection of the transplanted organ. The effect of rosuvastatin is increased if used together with ciclosporin). **Do not take Lypstaplus while taking ciclosporin.**
- Regorafenib (used to treat cancer)
- Anticoagulants (e.g. warfarin, acenocoumarol or fluindione, ticagrelor or clopidogrel): medicine to prevent blood clots.
- Other medicines to lower your cholesterol called fibrates, which correct also blood triglyceride levels (e.g. gemfibrozil and other fibrates). When gemfibrozil is taken together with this medicine, the effect of rosuvastatin is increased.
- Cholestyramine (a medicine for lowering cholesterol), because it affects the way ezetimibe works.

- Any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination (please see "Warnings and precautions"): ritonavir, lopinavir, atazanavir, simeprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
- Indigestion remedies containing aluminium and magnesium (used to neutralise acid in your stomach; they decrease the plasma level of rosuvastatin.) This effect may be mitigated with taking this type of medicine 2 hours after rosuvastatin.
- Erythromycin (an antibiotic). The effect of rosuvastatin is reduced when taken together with this antibiotic.
- Itraconazole or fluconazole (an antifungal). The effect of rosuvastatin is increased when taken together with any of these antifungal medicines.
- Fusidic acid. 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 Lypstaplus. Taking this medicine with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- An oral contraceptive (the pill). The levels of sexual hormones absorbed from the pill are increased.
- Hormone replacement therapy (increased hormone levels in the blood).
- Colchicine (used to treat and prevent gout).
- Daptomycin (an anitibiotic)

If you go into hospital or receive treatment for another condition, tell the medical staff that you are taking Lypstaplus.

Lypstaplus with food

Lypstaplus may be given at any time of the day, with or without food.

Pregnancy, breastfeeding and fertility

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

If you are a woman of childbearing age and are taking Lypstaplus, use a proven method of birth

control to avoid pregnancy.

Lypstaplus may affect your developing baby if you take it during pregnancy.

If you become pregnant while you are taking Lypstaplus, stop taking it and tell your doctor immediately.

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 Lypstaplus.

Driving and using machines

There have been side effects such as dizziness reported with Lypstaplus hat may affect your ability to drive or operate machinery.

It is not always possible to predict to what extent Lypstaplus 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 Lypstaplus affected them (see "Possible side effects").

Lypstaplus contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Lypstaplus

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

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

You should keep on being on a low-cholesterol diet and doing exercises and continue on this diet while taking Lypstaplus.

The usual dose for adults is one film-coated tablet per day.

You can take it at any time of the day, with or without food. Swallow each film-coated tablet whole with a drink of water.

Take your medicine at the same time every day.

This medicine is not suitable to start a treatment. Treatment initiation or dose adjustment if necessary should only be done by giving the active substances separately and after setting the appropriate doses the switch to Lypstaplus of the appropriate strength is possible.

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

Regular cholesterol checks

It is important to go back to your doctor for regular cholesterol checks to make sure your cholesterol has reached and is staying at the correct level.

If you take more Lypstaplus than you should

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

If you forget to take Lypstaplus

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

If you have missed a dose of Lypstaplus, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If **you stop taking Lypstaplus**

Talk to your doctor if you want to stop taking Lypstaplus. Your cholesterol levels might increase again if you stop taking Lypstaplus.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Lypstaplus can have side effects

Not all side effects reported for Lypstaplus are included in this leaflet. Should your general health

worsen or if you experience any untoward effects while taking Lypstaplus, please consult your health care provider for advice.

If any of the following happens, stop taking Lypstaplus 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 Lypstaplus. 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:

- chest pain
- shortness of breath
- breathing problems including persistent cough and/or shortness of breath or fever
- yellowing of the skin and eyes Uaundice) and tiredness which may be symptoms of liver problems.

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
- dizziness
- muscle pain
- feeling tired
- feeling weak
- 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.)

- stomach ache (abdomnial pain)
- constipation
- feeling sick (nausea)
- diarrhoea
- flatulence or wind

Less frequent side effects:

- elevations in some laboratory blood tests of muscle function (creatine phosphokinase (CPK) test)
- cough
- indigestion
- heartburn
- joint pain
- muscle spasms
- neck pain
- decreased appetite
- pain
- back pain
- muscle weakness
- muscle injury
- pain in arms and legs
- pain in a joint
- hot flush
- high blood pressure
- tingling sensation
- dry mouth
- inflammation of the stomach (gastritis)
- swelling, especially in the hands and feet
- elevations in some laboratory blood tests of liver function (transaminases)

- viral infection
- sore throat (pharyngitis)
- inflammation (irritation and swelling) of the sinuses (sinusitis)
- reduction in blood platelets
- inflammation of the pancreas, which causes a severe stomach pain which can extend to the back (pancreatitis)
- inflammation of the liver (hepatitis)
- traces of blood in your urine
- damage to the nerves of your legs and arms (such as numbness)
- memory loss
- breast enlargement in men (gynecomastia)
- Unusual muscle aches or pains which go on for longer than you might expect. Rarely this can develop into potentially life threatening muscle damage known as rhabdomyolysis, which leads to malaise, fever and kidney impairment.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).
- Muscle rupture.

Frequency not knowns:

- swelling caused by fluid held in the tissues (oedema)
- sleep disturbances, including insomnia and nightmares
- depression
- sexual difficulties
- tendon injury
- muscle weakness that is constant
- elevated levels of protein in the urine
- gallstones or inflammation of the gallbladder (which may cause stomach ache, nausea, vomiting)
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

Reporting of **side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction 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 !,ypstaplus

5. How to store Lypstaplus

Store all medicines out of reach of children.

Store below 30 °C.

Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date "EXP" which is stated on the carton box and the blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information What Lypstaplus contains

The active substances are rosuvastatin (as rosuvastatin calcium) and ezetimibe.

Lypstaplus 10 mg/10 mg: Each film-coated tablet contains rosuvastatin calcium equivalent to 10 mg

rosuvastatin and 10 mg ezetimibe.

Lypstaplus 20 mg/10 mg Each film-coated tablet contains rosuvastatin calcium equivalent to 20 mg rosuvastatin and 10 mg ezetimibe.

The other ingredients are:

Rosuvastatin - Core

Starch, pregelatinised (maize); Microcrystalline Cellulose (E460); Meglumine; Calcium hydrogen phosphate dihydrate (E341); Crospovidone (E1202); Colloidal anhydrous silica (E551); Sodium stearyl fumarate

Ezetimibe - Core

Mannitol (E421); Butylhydroxyanisole (E320); Sodium laurilsulfate (E487); Croscarmellose sodium (E468); Povidone (K-30) (E1201); Iron oxide red (E172); Magnesium stearate (E470 b); Sodium stearyl fumarate

Tablet coating

Hypromellose (E464); Titanium dioxide (E171); Macrogol 4000; Iron oxide red (E172)

What Lypstaplus looks like and contents of the pack

Lypstaplus 10 mg/10 mg film-coated tablets are pink coloured round shaped film-coated tablets with a diameter of 10.1 mm embossed with "AL" on one side.

Lypstaplus 20 mg/10 mg film-coated tablets are pink coloured round shaped film-coated tablets with a diameter of 10.6 mm and plain on both sides.

OPA/Al/PVC-Al blister packs

Packs of 10, 30, 60, 90, 100 film-coated tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Abbott Laboratories S.A. (Pty) Limited

Abbott Place

219 Golf Club Terrace

Constantia Kloof 1709

Applicant: Abbott Laboratories S.A (Pty) Ltd
Product name: Lypstaplus
Dosage form & **strength:** 10 mg rosuvastatin/10 mg ezetimibe film-coated tablets & 20 mg rosuvastatin /10 mg ezetimibe film-coated tablets

South Africa

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