

Consumer Medication Information Leaflet (RiMUP)

LYPSTAPLUS® (EZETIMIBE/ ROSUVASTATIN) FILM-COATED TABLET

-Ezetimibe/Rosuvastatin (10mg/10mg,10mg/20mg)

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What Lypstaplus® is used for

Lypstaplus® contains two different active substances: rosuvastatin (belongs to the group called 'statins') and ezetimibe (a cholesterol absorption inhibitor). They are both used to lower levels of total cholesterol, "bad" cholesterol (LDL cholesterol) and fatty substances called triglycerides in the blood. In addition, Lypstaplus® raises levels of "good" cholesterol (HDL cholesterol).

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

How Lypstaplus® works

Lypstaplus® works by reducing the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself. Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL and HDL cholesterol.

Before you use Lypstaplus®

When you must not use it

Do not take Lypstaplus® if you:

- are allergic to rosuvastatin or ezetimibe or any of the other ingredients of Lypstaplus® (listed in Product Description).

- have active liver disease
- are pregnant, trying to become pregnant or are breastfeeding.
- have severe kidney problem
- have repeated or unexplained muscle aches or pains.
- are receiving ciclosporin.

If any of the above applies to you (or you are in doubt), please go back and see your doctor.

Before you start to use it

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

- have ever been told that you have problems with your kidney.
- have had unexplained muscle aches or pains, a history of muscle aches or pains or a previous history of muscle problems when taking other cholesterol-lowering medicines.
- regularly drink large amounts of alcohol.
- your thyroid gland is not working properly.
- take other medicines called fibrates to lower your cholesterol.
- are over 70 years

Taking other medicines

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines including any you bought without a prescription.

It is especially important to tell your doctor if you are taking any of the following:

- ciclosporin (used for example, after organ transplants).
- gemfibrozil and other lipid-lowering products.
- antacid (used to neutralise acid in your stomach).
- erythromycin or fusidic acid (antibiotics)
- protease inhibitors (medicines used to fight the HIV infection)
- medicines with an active ingredient to prevent blood clots, such as warfarin or

- fluindione (anticoagulants)
- cholestyramine (also used to lower cholesterol)
- oral contraceptive or hormone replacement therapy

How to use Lypstaplus®

How much to use

Your doctor will determine the appropriate strength for you, depending on your condition, your current treatment and your personal risk status.

The recommended dose is one tablet per day.

When to use it

Take Lypstaplus® at the same time of each day, with or without food.

Swallow the tablet whole with a glass of water.

How long to use it

Continue taking Lypstaplus® for as long as your doctor recommends.

Lypstaplus® should be taken as directed by your health care provider. Continue taking your other cholesterol-lowering medicines unless your doctor tells you to stop.

If you forget to take it

Try to take Lypstaplus® as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet daily.

If you take too much (overdose)

If you have taken more Lypstaplus® than you should or if someone else has taken your medicine, tell your doctor or pharmacist or contact your nearest hospital.

While you are using it

Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking Lypstaplus®.

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- Tell your doctor immediately if you become pregnant while taking this medication.
- It is important to have your cholesterol measured regularly, even if you are taking medication to treat high cholesterol. You should also know your cholesterol levels and goals.

Tell your doctor immediately if you have the signs of Immune-mediated necrotizing myopathy (IMNM).

- prolonged proximal muscle weakness and elevated serum creatine kinase persist despite discontinuation of statin treatment.
- muscle biopsy showing necrotizing myopathy without significant inflammation;
- improvement with immunosuppressive agents

Things you must not do

- Do not take Lypstaplus® if you are hypersensitive (allergic) to Lypstaplus® or any of its ingredients.
- Do not stop taking the medicine unless advised by your doctor.
- Do not give Lypstaplus® to anyone else, even if they have the same symptoms or condition as you.
- Do not take other medications together with Lypstaplus® without speaking to your doctor or pharmacist first.

Things to be careful of

Contact your physician promptly if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasions, muscle problems can be serious, including muscle breakdown resulting in kidney damage that can lead to death.

Pregnancy and breastfeeding

Do not take Lypstaplus® if you

are pregnant, trying to become pregnant or are breastfeeding. If you become pregnant while taking Lypstaplus® stop taking it immediately and tell your doctor.

Driving or using machines

Lypstaplus® has negligible influence on the ability to drive and use machines. However, when driving or operating machines, it should be taken into account that dizziness may occur during treatment.

Side effects

In clinical studies, Lypstaplus® was generally well tolerated. The side effects were usually mild, temporary, and similar in type and frequency to side effects in patients who were given ezetimibe alone or rosuvastatin alone.

Common side effects (these may affect between 1 in 10 and 1 in 100 patients):

- Headache
- Dizziness
- Muscle pain
- Stomach pain
- Diarrhoea
- Flatulence
- Feeling tired, weak, or sick
- Constipation
- Nausea
- Elevations in some laboratory blood tests of liver (transaminases)
- Elevation in blood glucose levels

Uncommon side effects (these may affect between 1 in 100 and 1 in 1,000 patients):

- Skin rash
- Itching
- Hives
- Elevation in blood tests of liver function
- Cough
- Indigestion
- Decreased appetite
- Dry mouth
- Heartburn

- Nausea
- Joint, neck, chest or back pain
- Muscle spasms
- Muscle weakness
- Hot flush
- High blood pressure
- Tingling sensation
- Swelling in the arms, ankles or legs

Rare side effects (these may affect between 1 in 1,000 and 1 in 10,000 patients):

- Allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, itching of the skin (with raised lumps). If you think you are having an allergic reaction, stop taking Lypstaplus® and seek medical help immediately.
- Muscle damage in adults – as a precaution, stop taking Lypstaplus® and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected
- Low platelet count in blood
- A severe stomach pain (inflamed pancreas)
- Increase in liver enzymes in the blood
- Memory loss, forgetfulness, amnesia, memory impairment, confusion
- High sugar in the blood, increased fasting blood sugar level

If you have muscle problems that do not go away even after your doctor has told you to stop taking Lypstaplus®, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

If any of the side effects become troublesome, or if you experience any side effects not listed in this leaflet, please tell your doctor or

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pharmacist.

If you are prescribed Lypstaplus®, your healthcare professional may want to conduct routine blood tests to check your liver function before and after starting treatment.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03- 78835447, or visiting the website npra.gov.my (Consumers → Reporting).

Storage and Disposal of LYPSTAPLUS®

Storage

Keep out of the reach and sight of children.

Do not use Lypstaplus® after the expiry date which is stated on the box/blisters after EXP. The expiry date refers to the last day of the month.

Store your tablets below 30°C. Store in the original package in order to protect from light and moisture.

Disposal

Remember to return any unused medicine to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Lypstaplus® 10 mg/10 mg film-coated tablets:

Pink coloured round shaped film-coated tablet with a diameter of 10.1 mm embossed with “AL” on one side.

Lypstaplus® 20 mg/10 mg film-coated tablets:

Pink coloured round shaped film-coated tablet with a diameter of 10.6 mm plain on both sides.

Packs of 10, 30, 60 film-coated tablets.

Not all pack sizes may be marketed.

Ingredients

The active ingredients are rosuvastatin and ezetimibe. These tablets contain rosuvastatin calcium equivalent to 10 mg or 20 mg of rosuvastatin, with 10 mg of ezetimibe.

The other ingredients are:

Tablet core:

Pregelatinised starch, microcrystalline cellulose, meglumine, calcium hydrogen phosphate dihydrate, crospovidone, colloidal anhydrous silica, sodium stearyl fumarate, mannitol, butylated hydroxyanisole, sodium lauryl sulfate, croscarmellose sodium, povidone (K-30), ferric oxide red, magnesium stearate, sodium stearyl fumarate.

Tablet coating:

Opadry Pink (04F540040) composed of hypromellose 2910 (E464), titanium dioxide (E171), macrogol (E1521), iron oxide red (E172).

MAL Number

Lypstaplus® 10 mg/10 mg film-coated tablets:
MALXXXXXXXXXX

Lypstaplus® 20 mg/10 mg film-coated tablets:
MALXXXXXXXXXX

Manufacturer and Product Registration Holder

Manufacturer

Medreich Limited Unit 3
No. 4/3 Avalahalli,
Anjanapura Post,
Kanakapura Road, Bengaluru,
IN-560 062, India

Product Registration Holder

Abbott Laboratories (M) Sdn. Bhd.
27-02, Level 27, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.

Date of Revision

19/09/2024

Serial Number

NPRA (R1) 24/021