PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

LYPOVAS 5 film-coated tablets

Contains sugar: lactose monohydrate 21.125 mg

LYPOVAS 10 film-coated tablets

Contains sugar: lactose monohydrate 42.25 mg

LYPOVAS 20 film-coated tablets

Contains sugar: lactose monohydrate 84.50 mg

LYPOVAS 40 film-coated tablets

Contains sugar: lactose monohydrate 169.00 mg

Read all this leaflet carefully before you start taking LYPOVAS

- 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.

- **LYPOVAS** 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 **LYPOVAS** is and what it is used for

2. What you need to know before you take **LYPOVAS**

3. How to take **LYPOVAS**

4. Possible side effects

5 How to store **LYPOVAS**

6. Contents of the pack and other information

1. What LYPOVAS is and what is it used for:

LYPOVAS tablets belong to a group of medicines called HMG-CoA reductase inhibitors, commonly known as, 'statins'. It contains the active substance called rosuvastatin. **LYPOVAS** tablets is used to correct the levels of fatty substances in the blood called lipids, the most common of which is cholesterol. There are different types of cholesterol found in the blood – 'bad' cholesterol (LDL-C) and 'good' cholesterol (HDL-C). **LYPOVAS** tablets can reduce the 'bad' cholesterol and increase the 'good' cholesterol. It works by helping to block your body's

production of ‘bad’ cholesterol. It also improves your body’s ability to remove it from your blood.

*You have been prescribed **LYPOVAS** tablets because:*

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke.
- Changing your diet and doing more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking **LYPOVAS** tablets.
- You have other factors that increase your risk of having a heart attack, stroke, or related health problems.
- Heart attack, stroke and other problems can be caused by a disease called atherosclerosis. Atherosclerosis is due to build-up of fatty deposits in your arteries.

2. What you need to know before you take LYPOVAS:

Do not take LYPOVAS:

- if you are allergic to rosuvastatin, or any of the other ingredients of **LYPOVAS** (listed in section 6).
- if you are pregnant or breast-feeding. If you become pregnant while taking **LYPOVAS** tablets stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking **LYPOVAS** tablets by using

suitable contraception.

if you have liver disease

- if you have severe kidney problems
- if you have repeated or unexplained muscle aches or pains.
- if you take ciclosporin (used, for example, after organ transplants)

*In addition, do not take **LYPOVAS** 40 mg tablets (the highest dose)*

- if you have moderate kidney problems (if in doubt, please ask your doctor)
- if your thyroid gland is not working properly
- if you have had any 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.
- if you regularly drink large amounts of alcohol
- if you are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- if you take other medicines called fibrates to lower your cholesterol.

Warnings and precautions

Take special care with **LYPOVAS** if you:

- have problems with your kidneys.
- have problems with your liver.

- 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.
- regularly drink large amounts of alcohol.
- your thyroid gland is not working properly.
- take medicines used to fight the HIV infection e.g. combinations of ritonavir with atazanavir, lopinavir, and/or tipranavir, see 'Other medicines and **LYPOVAS** tablets.
- 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 **LYPOVAS** can lead to serious muscle problems (rhabdomyolysis), please see 'Other medicines and **LYPOVAS** tablets.
- are over 70 (as your doctor needs to choose the right start dose of **LYPOVAS** tablets to suit you)
- have severe respiratory failure.
- are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of **LYPOVAS** tablets to suit you.

Your doctor will usually carry out the blood test (liver function test) before and during treatment with **LYPOVAS** tablets.

While you are on **LYPOVAS** 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.

Children and adolescents:

- Children under 10 years old: **LYPOVAS** tablets should not be given to children younger than 10 years.
- Children below 18 years of age: The **LYPOVAS** 40 mg tablet is not suitable for use in children and adolescents below 18 years of age.
- Children can experience muscle soreness after physical activity, while taking **LYPOVAS**.

Other medicines and LYPOVAS:

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

- Ciclosporin (used for example, after organ transplants)
- Fibrates (such as gemfibrozil, fenofibrate) or any other medicine used to lower cholesterol (such as ezetimibe).
- Indigestion remedies (used to neutralise acid in your stomach)
- Erythromycin (an antibiotic)

- Fusidic acid (an antibiotic – please see warnings and precautions). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using **LYPOVAS**. Your doctor will tell you when it is safe to restart **LYPOVAS** tablets. Taking **LYPOVAS** tablets with fusidic acid may lead to muscle weakness, tenderness, or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.
- An oral contraceptive (the pill)
- Hormone replacement therapy
- Anti-viral medications such as ritonavir with lopinavir and/or atazanavir or simeprevir (used to treat infections, including HIV or hepatitis C infection – please see warnings and precautions). The effects of these medicines could be changed by **LYPOVAS** tablets or they could change the effect of **LYPOVAS** tablets.

Pregnancy and breastfeeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take **LYPOVAS** tablets if you are pregnant or breast feeding. If you become pregnant while taking **LYPOVAS** tablets stop taking it immediately

and tell your doctor. Women should avoid becoming pregnant while taking **LYPOVAS** tablets by using suitable contraception.

Driving and using machines:

LYPOVAS may cause dizziness, which may affect your ability to drive and use machines.

It is not always possible to predict to what extent **LYPOVAS** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **LYPOVAS** affects you.

LYPOVAS contains lactose:

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

3. How to take LYPOVAS:

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

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for:

Adults:

*If you are taking **LYPOVAS** tablets for high cholesterol:*

Your treatment with **LYPOVAS** tablets must start with the 5 mg. The choice of your start dose will depend upon:

- Your cholesterol levels.
- The level of risk you have of experiencing a heart attack or stroke.
- Whether you have a factor that may make you more sensitive to

Children and adolescents aged 10-17 years:

The dose range in children and adolescents aged 10 to 17 years is 5 to 20 mg once daily.

The usual start dose is 5 mg per day, and your doctor may increase your dose gradually to find the right amount of **LYPOVAS** tablets for you.

The maximum daily dose of **LYPOVAS** tablets is 10 mg or 20 mg for children aged 10 to 17 years depending on your underlying condition being treated. Take your dose once a day.

LYPOVAS tablets 40 mg tablet should not be used by children

Elderly:

Start treatment with one 5 mg tablet taken once a day.

Patients with kidney problems:

Start treatment with one 5 mg tablet taken once a day

Patients with liver problems

Start treatment with one 5 mg tablet taken once a day

Asian patients:

Start treatment with one 5 mg tablet taken once a day

Increasing the dose and maximum daily dose:

Your doctor may decide to increase your dose. This is so that you are taking the amount of Rosuvastatin tablets that is right for you. There will be a gap of four weeks between every dose adjustment.

Swallow each tablet whole with a drink of water.

Take **LYPOVAS** tablets once daily. You can take it at any time of the day with or without food. Try to take your tablet at the same time every day to help you to remember it.

If you take more LYPOVAS than you should:

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

In the event of suspected overdose, seek supportive medical care.

If you forget to take a dose of LYPOVAS:

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

If you forget to take a dose, take it as soon as you remember it.

However, if it is nearly time for the next dose, skip the missed dose.

If you stop taking LYPOVAS

Suddenly stopping your treatment with **LYPOVAS** may lead to your symptoms getting worse. Do not stop taking **LYPOVAS** unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.

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

4. Possible side effects

LYPOVAS can have side effects.

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

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

- Allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching)
- Skin inflammation, peeling and blistering

These are all very serious side effects. If you have them, you may have had a serious reaction to **LYPOVAS**. 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:

- unusual aches or pains in your muscles which go on for longer than you might expect. Muscle symptoms are more common in children and adolescents than in adults. As with other statins, a very small number of

people have experienced unpleasant muscle effects and rarely these have gone on to become a potentially life-threatening muscle damage known as rhabdomyolysis.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Stomach pain
- Constipation
- Feeling sick
- Feeling weak
- Dizziness
- 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.

Less frequent side effects:

- Rash, itching or other skin reactions.
- A severe stomach pain (inflamed pancreas).
- Jaundice (yellowing of the skin and eyes).
- Hepatitis (an inflamed liver).
- Damage to the nerves of your legs and arms (such as numbness).
- Joint pain.

- Memory loss.
- Breast enlargement in men (Gynecomastia)

Frequency unknown:

- Diarrhoea (loose stools).
- Steven-Johnson syndrome (serious blistering condition of the skin, mouth, eyes and genitals).
- Cough.
- Shortness of breath.
- Oedema (swelling).
- Sleep disturbances, including insomnia and nightmares.
- Sexual difficulties.
- Depression.
- Breathing problems, including persistent cough and/or shortness of breath or fever.
- Tendon injury.
- Muscle weakness that is constant.

Laboratory results:

***LYPOVAS** can cause the following changes to your lab results which your doctor will inform you about:*

- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your **LYPOVAS** tablets (only **LYPOVAS** tablets 40 mg)

Less frequent

- An increase in the amount of protein in the urine – this usually returns to normal on its own without having to stop taking your **LYPOVAS** tablets (only **LYPOVAS** tablets 5 mg, 10 mg and 20 mg).
- Increase in liver enzymes in the blood.
- Low platelet count in blood (thrombocytopenia*)*

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 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 **LYPOVAS**.

5. **How to store LYPOVAS**

- Keep out of reach and sight of children.
- Store at or below 25 °C in original container. Protect from moisture.

- This medication does not require any special storage conditions
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What LYPOVAS 5, 10, 20, 40 mg contains:

The active substance: Rosuvastatin (as rosuvastatin calcium)

The other ingredients are:

- Cellulose microcrystalline,
- crospovidone,
- lactose monohydrate,
- magnesium stearate,
- sodium hydrogen carbonate,
- Opadry II pink contains:
    - Hypromellose,
    - iron oxide red,
    - lactose monohydrate
    - titanium dioxide,
    - triacetin.

What LYPOVAS looks like and contents of the pack

Film-coated tablets

LYPOVAS 5

Pink, 4.50 mm, round, biconvex, bevelled edge, film-coated tablet, debossed with ‘R5’ on one side and plain on other side

LYPOVAS 10

Pink, 5.50 mm, round, biconvex, bevelled edge, film-coated tablet, debossed with ‘R10’ on one side and plain on other side.

LYPOVAS 20

Pink, 7.00 mm, round, biconvex, film-coated tablet, debossed with ‘R20’ on one side and plain on other side.

LYPOVAS 40

Pink, 11.50 mm X 6.90 mm, oval, biconvex, film-coated tablet, debossed with ‘R40’ on one side and plain on other side.

LYPOVAS 5, 10, 20 & 40

Blister packs of 10’s, 28’s, 30’s, 56’s, 84’s: alurnpack-GDO cold forming base foil 198 mm (25µ OPA/50µ AJ/60µ PVC) & aluminium lid foil 198 mm (Zeon 25u foil 7 esm HSL DSO).

Not all pack sizes may be marketed

Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) LTD

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

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LYPOVAS 40: 55/7.5/0566

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **LYPOVAS**