

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

LDNIL 5/ 10/ 20/ 40 (Rosuvastatin Tablets 5 mg/ 10 mg/ 20 mg/ 40 mg)

**Read all of this leaflet carefully before you or your child start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you or your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your or your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **In this leaflet:**

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### **1) WHAT IS LDNIL AND WHAT IS IT USED FOR?**

LDNIL belongs to a group of medicines called statins.

You have been prescribed LDNIL because:

- You have a high cholesterol level. This means you are at risk from a heart attack or stroke.

You have been advised to take a statin, because changing your diet and taking more exercise were not enough to correct your cholesterol levels. You should continue with your cholesterol-lowering diet and exercise while you are taking LDNIL.

#### **Or**

- 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.

### **Why is it important to keep taking LDNIL?**

LDNIL 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).

- LDNIL 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.

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

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.

You need to keep taking LDNIL, even if it has got your cholesterol to the right level, because it prevents your cholesterol levels from creeping up again and causing build up of fatty deposits. However, you should stop if your doctor tells you to do so, or you have become pregnant.

## **2) BEFORE YOU TAKE LDNIL**

### **Do not take LDNIL:**

- If you have ever had an allergic reaction to LDNIL, or to any of its ingredients.
- If you are pregnant or breast-feeding. If you become pregnant while taking LDNIL stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking LDNIL 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 a drug called ciclosporin (used, for example, after organ transplants)

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

In addition, do not take LDNIL 40 mg (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.

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

**Take special care with LDNIL:**

- If you have problems with your kidneys.
- If you have problems with your liver.
- If you 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.
- If you regularly drink large amounts of alcohol.
- If your thyroid gland is not working properly.
- If you take other medicines called fibrates to lower your cholesterol. Please read this leaflet carefully, even if you have taken other medicines for high cholesterol before.
- If you take medicines used to fight the HIV infection e.g. lopinavir/ritonavir, please see Taking other medicines.
- If the patient is under 10 years old: LDNIL should not be given to children younger than 10 years.
- If the patient is below 18 years of age: The LDNIL 40 mg tablet is not suitable for use in children and adolescents below 18 years of age.
- If you are over 70 (as your doctor needs to choose the right start dose of LDNIL to suit you)
- If you have severe respiratory failure.
- If you are of Asian origin – that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the right start dose of LDNIL to suit you.

If any of the above applies to you (or if you are not sure):

- **Do not take LDNIL 40 mg (the highest dose) and check with your doctor or pharmacist before you actually start taking any dose of LDNIL.**

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 usually carry out this blood test (liver function test) before and during treatment with LDNIL.

**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.

Tell your doctor if you are taking any of the following: ciclosporin (used for example, after organ transplants), warfarin (or any other drug used for thinning the blood), 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), an oral contraceptive (the pill), hormone replacement therapy or lopinavir/ritonavir (used to fight the HIV infection – please see Take special care with LDNIL). The effects of these medicines could be changed by LDNIL or they could change the effects of LDNIL.

### **Taking LDNIL with food and drink**

You can take LDNIL with or without food.

### **Pregnancy and breast-feeding**

Do not take LDNIL if you are pregnant or breast-feeding. If you become pregnant while taking LDNIL stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking LDNIL by using suitable contraception.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Most people can drive a car and operate machinery while using LDNIL – it will not affect their ability. However, some people feel dizzy during treatment with LDNIL. If you feel dizzy, consult your doctor before attempting to drive or use machines.

### **Important information about some of the ingredients of LDNIL**

If you have been told by your doctor that you have an intolerance to some sugars (lactose or milk sugar), contact your doctor before taking LDNIL.

For a full list of ingredients please see Further information below.

## **3) HOW TO TAKE LDNIL**

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

### **Usual doses in adults**

#### **If you are taking LDNIL for high cholesterol:**

#### **Starting dose**

Your treatment with LDNIL must start with the 5 mg or the 10 mg dose, even if you have taken a higher dose of a different statin before. The choice of your start dose will depend upon:

- Your cholesterol level.

- 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 possible side effects.

Please check with your doctor or pharmacist which start dose of LDNIL will best suit you.

Your doctor may decide to give you the lowest dose (5 mg) if:

- You are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- You are over 70 years of age.
- You have moderate kidney problems.
- You are at risk of muscle aches and pains (myopathy).

### **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 LDNIL that is right for you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg, then 20 mg and then 40 mg if necessary. If you started on 10 mg, your doctor may decide to double this to 20 mg and then 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of LDNIL is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

### **If you are taking LDNIL to reduce your risk of having a heart attack, stroke or related health problems:**

The recommended dose is 20 mg daily. However, your doctor may decide to use a lower dose if you have any of the factors mentioned above.

### **Usual doses in children aged 10-17 years**

The usual start dose is 5 mg. Your doctor may increase your dose to find the right amount of LDNIL for you. The maximum daily dose of LDNIL is 20 mg. Take your dose once a day. LDNIL 40 mg tablet should not be used by children.

### **Taking your tablets**

Swallow each tablet whole with a drink of water.

Take LDNIL once daily. You can take it at any time of the day.

Try to take your tablet at the same time every day to help you to remember it.

### **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.

Your doctor may decide to increase your dose so that you are taking the amount of LDNIL that is right for you.

**If you take more LDNIL than you should**

Contact your doctor or nearest hospital for advice.

If you go into hospital or receive treatment for another condition, tell the medical staff that you're taking LDNIL.

**If you forget to take LDNIL**

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

**If you stop taking LDNIL**

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

**4) POSSIBLE SIDE EFFECTS**

Like all medicines, LDNIL can cause side effects, although not everybody gets them.

It is important that you are aware of what these side effects may be. They are usually mild and disappear after a short time.

Stop taking LDNIL and seek medical help immediately if you have any of the following allergic reactions:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- Severe itching of the skin (with raised lumps).

Also, stop taking LDNIL and talk to your doctor immediately if you have any 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.

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

- Headache
- Stomach pain
- Constipation

- Feeling sick
- Muscle pain
- Feeling weak
- Dizziness
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your LDNIL tablets (only LDNIL 40 mg)
- Diabetes, mostly in those with blood sugar at the upper end of “normal”

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

- Rash, itching or other skin reactions
- An increase in the amount of protein in the urine - this usually returns to normal on its own without having to stop taking your LDNIL tablets (only LDNIL 5 mg, 10 mg and 20 mg).

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

- Severe allergic reaction – signs include swelling of the face, lips, tongue and/or throat, difficulty in swallowing and breathing, a severe itching of the skin (with raised lumps). If you think you are having an allergic reaction, then stop taking LDNIL and seek medical help immediately.
- Muscle damage in adults – as a precaution, stop taking LDNIL and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than expected.
- A severe stomach pain (inflamed pancreas)
- Increase in liver enzymes in the blood.

**Very rare possible side effects (these may affect less than 1 in 10,000 patients):**

- Jaundice (yellowing of the skin and eyes)
- Hepatitis (an inflamed liver)
- Traces of blood in your urine
- Damage to the nerves of your legs and arms (such as numbness)
- Joint pain
- Memory loss

**Side effects of unknown frequency may include:**

- Diarrhoea (loose stools)
- Stevens-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

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 pharmacist.

### **5) HOW TO STORE LDNIL**

- Keep out of the reach and sight of children.
- Do not use LDNIL after the expiry date which is stated on the box/blisters/label after EXP. The expiry date refers to the last day of the month.
- Tablets should not be thrown in your bin or put down the drain. If they are out of date, or no longer suitable for you, return them to your pharmacist.
- Store your tablets below 30°C.
- If your tablets come in a plastic container, keep the lid tightly closed.
- Keep your tablets in the container you received them in.

### **6) FURTHER INFORMATION**

#### **What LDNIL contains:**

The active substance in LDNIL is rosuvastatin. LDNIL film-coated tablets contain rosuvastatin calcium equivalent to 5 mg, 10 mg, 20 mg or 40 mg of rosuvastatin. The other ingredients are: Microcrystalline Cellulose (Avicel PH 101), Pregelatinized starch, Crospovidone, Meglumine, Mannitol, Magnesium Stearate. LDNIL 10 mg, 20 mg and 40 mg film-coated tablets also contain red iron oxide. LDNIL 5 mg film-coated tablets also contain yellow iron oxide.

#### **What LDNIL looks like and contents of the pack**

LDNIL comes in four tablet strengths:

LDNIL 5 mg film-coated tablets are yellow, round and biconvex plain surface on both sides.

LDNIL 10 mg film-coated tablets are pink, round and biconvex plain surface on both sides.

LDNIL 20 mg film-coated tablets are pink, round and biconvex plain surface on both sides.

LDNIL 40 mg film-coated tablets are pink, oval and biconvex plain surface on both sides.

Blister pack of 3 X 10's in a unit cartons.