PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NOVATIN 5 mg (Tablet)

NOVATIN 10 mg (Tablet)

NOVATIN 20 mg (Tablet)

NOVATIN 40 mg (Tablet)

NOVATIN 80 mg (Tablet)

Read all of this leaflet carefully before you start taking NOVATIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- NOVATIN 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.

1. WHAT NOVATIN CONTAINS

The active substance is simvastatin.

NOVATIN 5 mg: Each film-coated tablet contains simvastatin 5 mg.

NOVATIN 10 mg: Each film-coated tablet contains simvastatin 10 mg.

NOVATIN 20 mg: Each film-coated tablet contains simvastatin 20 mg.

NOVATIN 40 mg: Each film-coated tablet contains simvastatin 40 mg.

NOVATIN 80 mg: Each film-coated tablet contains simvastatin 80 mg.

The other ingredients are ascorbic acid; butylhydroxyanisole; citric acid monohydrate; hydroxypropylcellulose; hypromellose; lactose monohydrate; magnesium stearate; microcrystalline cellulose; starch pregelatinised; talc.

Colourants: NOVATIN 5 mg: Iron oxide yellow,titanium dioxide.
NOVATIN 10 mg & 20 mg: Iron oxide red, iron oxide yellow, titanium dioxide.
NOVATIN 40 mg & 80 mg: Iron oxide red, titanium dioxide.

NOVATIN is sucrose free. NOVATIN contains lactose monohydrate.

2. WHAT NOVATIN IS USED FOR

NOVATIN contains simvastatin which lowers the cholesterol levels in your blood by preventing the production of cholesterol.

NOVATIN is used, in combination with a controlled diet, if you have:

- raised levels of cholesterol (primary hypercholesterolaemia),
- raised levels of cholesterol and other fats called triglycerides in your blood (mixed hyperlipidaemia),
- a hereditary disorder which causes raised levels of cholesterol in your blood (heterozygous familial hypercholesterolaemia),
- coronary heart disease where the arteries that supply your heart muscle with blood and oxygen (coronary arteries) are not functioning optimally because they have been narrowed.

If you suffer from or are at risk of developing coronary heart disease and have hypercholesterolaemia, NOVATIN may:

- prolong your life by reducing the risk for total loss of function of your coronary arteries,
- reduce your risk of having a heart attack,
- slow the progression of the narrowing of your coronary arteries, and
- reduce your risk for needing coronary artery bypass surgery.

3. BEFORE YOU TAKE NOVATIN

Do not take NOVATIN:

- If you are hypersensitive (allergic) to simvastatin, other medicines belonging to the same class as simvastatin called HMG-CoA reductase inhibitors which lowers blood cholesterol levels, or any of the ingredients of NOVATIN.
- If you have acute or chronic liver disease.
- If you experience unexplained persistent elevation of serum transaminases (liver enzymes).
- If you are pregnant or breastfeeding.
- If you suffer from an inherited disorder called porphyria which affect the production of certain enzymes in your body and consequently impair your ability to metabolise certain medicines. Safety of NOVATIN has not been established in patients with porphyria.
- If you are taking any of the following medicines: itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin, nefazodone, gemfibrozil, ciclosporin, or danazol.

Ask your doctor if you are not sure if your medicine is listed above.

Take special care with NOVATIN:

- If there is a possibility that you may become pregnant or are planning to have a baby, you must tell your doctor before taking NOVATIN (see **"Pregnancy and breastfeeding"**).
- Children should not be using NOVATIN since the safety and effectiveness of NOVATIN in children have not been established.
- Increases in blood sugar levels have been reported with the use of NOVATIN. If you have diabetes or are at risk of developing diabetes (e.g. you have high blood sugar levels, are overweight, have raised levels of fats called triglycerides in your blood, or suffer from high blood pressure) your doctor should monitor your blood sugar levels.
- There have been reports of interstitial lung disease, a lung condition which affects the space around the air sacs of the lungs, in patients taking NOVATIN. Inform your doctor promptly if you experience difficulty breathing, develop a dry cough, or if your general health worsen.
- If you develop unexplained muscle pain, tenderness or weakness, particularly if accompanied by a general feeling of being unwell and fever, report this promptly to your doctor or pharmacist. You should especially be aware of these symptoms if you are taking NOVATIN 80 mg. Your doctor will do blood tests and may tell you to stop taking NOVATIN if you experience muscle problems.
- If your doctor has told you to stop taking NOVATIN because of muscle problems, promptly inform your doctor if the symptoms do not go away.
- If you are elderly (age ≥ 65 years), a female, have thyroid problems, have kidney problems, a history of hereditary muscle disorders, have previously experienced muscle problems with the use of cholesterol-lowering medicines called statins and fibrates, or you drink too much alcohol, inform your doctor before you start taking NOVATIN. Your doctor will do blood tests and determine if you can you use NOVATIN.
- If you have a serious infection, low blood pressure, metabolic, hormonal or electrolyte problems, uncontrolled epilepsy, have experienced physical trauma or will be having major surgery, tell your doctor. Your doctor may advise you to stop taking NOVATIN for a few days.
- It is very important that if you are already taking any other medicine to inform your doctor before you start taking NOVATIN. There are certain medicines that, when used together with NOVATIN, increase the levels of NOVATIN in your blood and consequently the risk of serious side effects involving your muscles (myopathy) and kidneys (rhabdomyolysis). Refer to "**Taking other medicines with NOVATIN**" below for the list of medicines.

- If you suffer from liver disease, and if you consume substantial amounts of alcohol and/or have a history of liver disease.
- There have been reports of serious liver problems in patients taking NOVATIN. Patients should notify their healthcare professional right away if they have the following symptoms: unusual fatigue or weakness; loss of appetite; upper belly pain; dark-coloured urine; or yellowing of the skin or the whites of the eyes.

Taking NOVATIN with food and drink:
Avoid drinking grapefruit juice when you are taking NOVATIN. Large quantities of grapefruit juice (e.g. more than 1 litre per day) may increase the levels of NOVATIN in your blood and consequently increase your risk of developing muscle and kidney problems. Refer to "**Take special care with NOVATIN**" above, for more information.

Pregnancy and breastfeeding:
Safety of NOVATIN in pregnant and breastfeeding women has not been established.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking NOVATIN.

Driving and using machinery:
NOVATIN may make you feel dizzy which can affect your ability to drive and operate machines.

Important information about some of the ingredients of NOVATIN:
NOVATIN contains a sugar known as lactose monohydrate. You should not take NOVATIN if you suffer from hereditary disorders which make you sensitive or intolerant to lactose e.g. galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. Tell your doctor or healthcare provider if you are suffering from such a disorder.

Taking other medicines with NOVATIN:
NOVATIN interacts with itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin, nefazodone, gemfibrozil, ciclosporin, and danazol.

NOVATIN should be taken 1 hour before or 4 hours after cholestyramine. Please consult your doctor if you are using immune-suppressants, fibrates or niacin.

In addition to the medicines listed above, tell your doctor if you are taking any of the following in particular:

- warfarin (to prevent blood clots)
- fenofibrate (a cholesterol-lowering medicine)
- niacin (a cholesterol-lowering medicine)
- rifampicin (antibiotic used for tuberculosis/TB)
- fluconazole (antifungal medicine)
- fusidic acid (antibiotic)
- digoxin or amiodarone (used for heart conditions)
- verapamil, diltiazem or amlodipine (used for high blood pressure and heart conditions)
- colchicine (used for gout).

You should also tell any doctor prescribing new medicine for you, that you are taking NOVATIN.

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

4. HOW TO TAKE NOVATIN

Always take NOVATIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of NOVATIN is too strong or too weak, tell your doctor or pharmacist.

You must follow a cholesterol lowering diet before initiation of, and while on NOVATIN therapy. Discuss this with your healthcare professional.

Hypercholesterolaemia:
Adults: Initial dose: 10 mg daily as a single dose in the evening.

Coronary Heart Disease:
Adults: Initial dose: 20 mg/day as a single dose in the evening.

Dosage adjustments:

If required, the dose should be adjusted at intervals of not less than 4 weeks, up to a maximum of 80 mg daily as a single dose in the evening.

NOVATIN can be taken with meals or on an empty stomach.

Do not share medicines prescribed for you with any other person. It may harm them.

If you take more NOVATIN 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 NOVATIN:

Do not take an extra dose; just take your normal amount of NOVATIN at the usual time the next day.

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

5. POSSIBLE SIDEEFFECTS

NOVATIN can have side effects.

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

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

Muscle problems:

- Muscle pain (myalgia), muscle cramps, muscle weakness which may continue even after therapy with NOVATIN has been stopped (myopathy, myositis, immune-mediated necrotising myopathy), break down of muscle tissue presenting as muscle pain with elevated creatine phosphokinase (a certain enzyme which indicate muscle breakdown) and myoglobinuria (brown coloured urine as a result of muscle protein in the urine) leading to renal/kidney failure (rhabdomyolysis). Muscle problems can be very serious and can lead to kidney damage and also death if left untreated.

Signs of allergic (hypersensitivity) reactions:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing (anaphylaxis, angio-oedema).
- Itchy, red skin rash known as hives (urticaria), flushing.
- Skin rash, blisters forming on the mucous membranes of the mouth, throat, eyes, anus and genital areas, peeling of the skin (erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis).
- Lupus-like syndrome which can include symptoms such as skin rash, sensitivity to the sun (photosensitivity), hair loss (alopecia), constant joint pain (arthritis or arthralgia), lung and kidney problems.
- Shortness of breath, tiredness (fatigue), general feeling of discomfort or being unwell (dyspnoea and malaise, haemolytic anaemia).
- Pain and stiffness of the neck, shoulders and hips (polymyalgia rheumatica).
- Skin eruptions and swelling (dermatomyositis).
- Abnormal bruising, red/purple discolouration on the skin, nosebleeds, bleeding gums (vasculitis, purpura, thrombocytopenia).
- Changes in red and white blood cells (increased erythrocyte sedimentation rate, eosinophilia, leukopenia).
- Blood tests show the presence of autoantibodies which indicates that the immune system is attacking the body (positive ANA).
- Fever and/or chills.

Inflammation or failure of the liver (hepatitis, hepatic failure):

- Yellowing of the skin and eyes (jaundice), itching, dark-coloured urine or pale coloured stool, weakness, loss of appetite.

Inflammation of the pancreas (pancreatitis):

- Abdominal pain, nausea, vomiting, fever.

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

The following side effects have been reported frequently:

- Difficulty sleeping (insomnia).

The following side effects have been reported less frequently:

- Depression, cognitive impairment (memory loss, forgetfulness, memory impairment, amnesia, confusion).
- Headache, damage to the nerves affecting sensation, movement and organ function (peripheral neuropathy).

The following side effects have been reported but the frequencies are unknown:

- Increases in HbA1c a blood component used to determine blood glucose/sugar levels, increases in fasting glucose/sugar levels, metabolic disorder which causes high blood glucose/sugar levels (diabetes mellitus).
- Constipation, diarrhoea, passing of wind (flatulence), dyspepsia, cramps, inflammation of the lining of the stomach (gastritis),
- Lung condition affecting the space around the air sacs of the lungs (interstitial lung disease), respiratory infection, inflammation of the mucous membranes in the lungs (bronchitis), inflammation of the nasal sinuses (sinusitis).
- Decrease in the amount red blood cells or haemoglobin in the blood which are necessary to transport oxygen to the rest of the body (anaemia), decrease in the number of white blood cells (neutropenia).
- Urinary tract infections.
- Erectile dysfunction which causes problems with sexual intercourse in male patients.
- Inflammation of the skin (eczema).
- Inflammation and tearing of the tendons (tendinopathy).
- Dizziness, pins and needles (paraesthesia).
- Abnormal heart rhythm (atrial fibrillation).
- Mass gain has been reported.
- Physical weakness (aesthenia), swelling caused by fluid retention (oedema).
- Marked and persistent increases of liver enzymes in the blood (serum transaminases and elevated alkaline phosphatase and gamma-glutamyltranspeptidase), however, the changes in liver function have generally been mild and transient; increases in blood levels of creatine kinase (CK) an enzyme used to determine if there has been muscle damage.

Memory loss and confusion have been reported with NOVATIN use.

6. STORING AND DISPOSING OF NOVATIN

Store at or below 30 °C.

DO NOT REMOVE BLISTERS FROM THE CARTON UNTIL REQUIRED FOR USE.

KEEP OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF NOVATIN

NOVATIN 5 mg:

1. PVC/ACLAR

Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.

Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 14 tablets.

Pack size 28's: Each carton contains 2 blisters of 14 tablets each.

2. PVC/PE/PVdC

Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.

Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 14 tablets.

Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

NOVATIN 10 mg:

1. PVC/ACLAR

Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.

Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 14 tablets.

Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

2. PVC/PE/PVdC

Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 10 tablets.

Pack size: 30’s: Each carton contains 3 blisters of 10 tablets each.
Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 14 tablets.
Pack size: 28’s: Each carton contains 2 blisters of 14 tablets each.

NOVATIN 20 mg:
1. PVC/ACLAR
Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 10 tablets.
Pack size: 30’s: Each carton contains 3 blisters of 10 tablets each.
Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 14 tablets.
Pack size: 28’s: Each carton contains 2 blisters of 14 tablets each.
2. PVC/PE/PVdC
Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 10 tablets.
Pack size: 30’s: Each carton contains 3 blisters of 10 tablets each.
Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 14 tablets.
Pack size 28’s: Each carton contains 2 blisters of 14 tablets each.

NOVATIN 40 mg:
1. PVC/ACLAR
Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 10 tablets.
Pack size: 30’s: Each carton contains 3 blisters of 10 tablets each.
Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 14 tablets.
Pack size 28’s: Each carton contains 2 blisters of 14 tablets each.
2. PVC/PE/PVdC
Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 10 tablets.
Pack size: 30’s: Each carton contains 3 blisters of 10 tablets each.

Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 14 tablets.
Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

NOVATIN 80 mg:

1. PVC/ACLAR

Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 10 tablets.
Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.
Tablets are packed in white opaque 250 micron PVC film laminated with 50 micron aclar and 25 micron printed aluminium foil. Each blister contains 14 tablets.
Pack size 28's: Each carton contains 2 blisters of 14 tablets each.

2. PVC/PE/PVdC

Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 10 tablets.
Pack size 30's: Each carton contains 3 blisters of 10 tablets each.
Tablets are packed in white opaque 250 micron PVC film laminated with 25 micron PE, coated with 60 gsm PVdC and 25 micron printed aluminium foil. Each blister contains 14 tablets.
Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

8. IDENTIFICATION OF NOVATIN

NOVATIN 5 mg: Yellow coloured, round shaped, biconvex, film-coated tablets, debossed with 'A' on one side and '15' on the other side.
NOVATIN 10 mg: Light pink coloured, round shaped, biconvex, film-coated tablets, debossed with A' on one side and '01' on the other side.
NOVATIN 20 mg: Light pink coloured, round shaped, biconvex, film-coated tablets, debossed with 'A' on one side and '02' on the other side.
NOVATIN 40 mg: Pink coloured, round shaped, biconvex, film-coated tablets, debossed with 'A' on one side and '03' on the other side.
NOVATIN 80 mg: Pink coloured, capsule shaped, biconvex, film-coated tablets, debossed with 'A' on one side and '04' on the other side.

9. REGISTRATION NUMBER/ REFERENCE NUMBER

NOVATIN 5 mg:41/7.5/0381

NOVATIN 10 mg: 41/7.5/0382

NOVATIN 20 mg: 41/7.5/0383

NOVATIN 40 mg: 41/7.5/0384

NOVATIN 80 mg: 41/7.5/0385

10.NAME AND ADDRESS OF THE REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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