PROFESSIONAL INFORMATION
NOVATIN

SCHEDULING STATUS:
S4

NOVAGEN
PHARMA

PROPRIETARY NAME AND DOSAGE FORM:
Novatin 5 (Tablet)
Novatin 10 (Tablet)
Novatin 20 (Tablet)
Novatin 40 (Tablet)
Novatin 80 (Tablet)

COMPOSITION:
NOVATIN 5: Each film-coated tablet contains simvastatin 5 mg.
NOVATIN 10: Each film-coated tablet contains simvastatin 10 mg.
NOVATIN 20: Each film-coated tablet contains simvastatin 20 mg.
NOVATIN 40: Each film-coated tablet contains simvastatin 40 mg.
NOVATIN 80: Each film-coated tablet contains simvastatin 80 mg.

Excipients:
Ascorbic acid, butylhydroxyanisole (antioxidant), citric acid monohydrate, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, starch pregelatinised, talc.

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

Contains sugar (lactose monohydrate).

PHARMACOLOGICAL CLASSIFICATION:
A 7.5 Serum-cholesterol reducers

PHARMACOLOGICAL ACTION:
Simvastatin is a cholesterol-lowering agent derived synthetically from a fermentation product of *Aspergillus terreus.*

Pharmacodynamic properties:
After oral ingestion simvastatin, an inactive lactone, is hydrolysed to the corresponding beta-hydroxy acid, the active form. This is a principal metabolite and an inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase, the enzyme that catalyses the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in the biosynthesis of cholesterol. As a result, simvastatin reduces total plasma cholesterol, low density lipoprotein (LDL)- and very low density lipoprotein (VLDL)-cholesterol concentrations. Apolipoprotein B is also decreased. In addition, simvastatin moderately increases high-density lipoprotein (HDL)-cholesterol and variably reduces plasma triglycerides.

Pharmacokinetic properties:
Absorption:
Following an oral dose, simvastatin is well absorbed and peak plasma concentrations of simvastatin are seen in 1 to 2 hours.
There is extensive first-pass extraction by the liver, with oral bioavailability of the active medicine or metabolites being less than 5 %.

Distribution:
More than 95 % of simvastatin and its beta-hydroxy metabolite are bound to plasma proteins.

Elimination:
Simvastatin is excreted primarily via the liver, and less than 13 % of its metabolites are excreted in the urine.

INDICATIONS:
Hypercholesterolaemia:
NOVATIN is indicated, in combination with diet, to decrease elevated serum total cholesterol and LDL-cholesterol in patients with:
- Primary hypercholesterolaemia,
- Heterozygous familial hypercholesterolaemia, or
- Mixed hyperlipidaemia,

when response to diet or other non-pharmacological measures alone are not adequate.

Coronary heart disease:
NOVATIN is indicated in patients with coronary heart disease and hypercholesterolaemia unresponsive to diet, to:
- reduce the risk of total mortality, by reducing coronary death,
- reduce the risk of non-fatal myocardial infarction,
- reduce the risk of undergoing myocardial revascularization procedures (coronary artery bypass grafting and percutaneous transluminal coronary angioplasty), and
- slow the progression of coronary atherosclerosis.

CONTRAINDICATIONS:
Hypersensitivity to simvastatin, other HMG-CoA reductase inhibitors, or any of the excipients in NOVATIN.
Acute or chronic liver disease.
Unexplained persistent elevation of serum transaminases.
Pregnancy and lactation (see **PREGNANCY AND LACTATION)**.
Porphyria: Safety has not been established.
Concomitant administration of strong CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin and nefazodone) (see **WARNINGS AND SPECIAL PRECAUTIONS,** and **INTERACTIONS).**
Concomitant administration of gemfibrozil, ciclosporin, or danazol **(**see **WARNINGS AND SPECIAL PRECAUTIONS,** and **INTERACTIONS).**

WARNINGS AND SPECIAL PRECAUTIONS:
Use in paediatric patients is not recommended as safety and efficacy have not been established.

Diabetes mellitus:
Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including NOVATIN.
Patients who are at risk of diabetes (i.e. fasting glucose 5,6 to 6,9 mmol/l, BMI > 30 kg/m^2, raised triglycerides, hypertension) should be carefully monitored.

Interstitial lung disease:
Cases of interstitial lung disease have been reported with some statins, including NOVATIN, especially with long term therapy. Presenting features include dyspnoea, non-productive cough and deterioration in general health (fatigue, weight loss and fever). If it is suspected a patient has developed interstitial lung disease, NOVATIN should be discontinued.

Myopathy/Rhabdomyolysis:
The risk of myopathy and rhabdomyolysis is dose related.
High plasma levels of HMG-CoA reductase inhibitors including NOVATIN increase the risk of myopathy. A creatine kinase (CK) level above 10 times the Upper Limit of Normal (ULN) in a patient, with unexplained symptoms (e.g. muscle pain, tenderness or weakness) indicates myopathy. In some cases, myopathy presents as rhabdomyolysis with or without acute renal failure secondary to myoglobinuria. Fatalities have been reported.

Patients should be advised of the increased risk of myopathy and rhabdomyolysis with NOVATIN and be informed to report promptly any unexplained muscle pain, tenderness or weakness. Treatment should be discontinued immediately when these symptoms occur.

There have been reports of immune-mediated necrotising myopathy (IMNM) which is an autoimmune myopathy associated with use of statins including NOVATIN.

Creatine kinase (CK) measurement:
To ensure accurate interpretation of creatine kinase (CK) levels, measurements should not be taken following strenuous exercise or in the presence of any other possible cause for CK increase. If CK levels are significantly elevated at baseline (> 5 x ULN), levels should be re-measured within 5 to 7 days later to confirm the results.

Before treatment:
Patients starting therapy with NOVATIN, or when the dose of NOVATIN needs to be increased, should be advised of the risk of myopathy, including rhabdomyolysis, and should promptly report unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever or if muscle signs and symptoms persist after discontinuing NOVATIN.

NOVATIN treatment should be initiated with caution in patients with predisposing factors for rhabdomyolysis. A baseline value for the CK level should be determined before starting treatment in the following situations:
- elderly (age ≥ 65 years),
- female gender,
- severe renal impairment,
- uncontrolled hypothyroidism,
- personal or familial history of hereditary muscular disorders,
- previous history of muscular toxicity with a statin or fibrate, and
- alcohol abuse.

Where predisposing factors exist, the risk of treatment should be carefully considered in relation to possible benefit. Clinical monitoring is recommended. If a patient has previously experienced a muscle disorder on a fibrate or a statin such as NOVATIN, treatment with a different member of the class should only be initiated with caution. If CK levels are significantly elevated at baseline (> 5 x ULN), treatment should not be started.

Whilst on treatment:
Measure CK values if muscle pain, weakness or cramps occur during treatment with NOVATIN. Treatment should be stopped if these levels are significantly elevated (> 5 x ULN) when measured in the absence of strenuous exercise.
Discontinuation of NOVATIN may be considered if muscular symptoms are severe and cause daily discomfort, even if CK levels are < 5 x ULN. NOVATIN should be discontinued if myopathy is diagnosed or suspected.
The re-introduction of NOVATIN or the introduction of an alternative statin at the lowest dose, in conjunction with close monitoring, may be considered if muscular symptoms resolve and CK levels return to normal.
Treatment with NOVATIN 80 is associated with a higher risk of myopathy. Periodic CK measurements are recommended as they may be useful to identify subclinical cases of myopathy. However, there is no assurance that such monitoring will prevent myopathy.
NOVATIN treatment should be discontinued temporarily in cases where a patient may be predisposed to developing renal failure secondary to rhabdomyolysis, such as severe acute infection (e.g. sepsis), hypotension, severe metabolic, endocrine or electrolyte disorders, uncontrolled seizures, major surgery or trauma. There is an increased risk of developing renal failure if rhabdomyolysis occurs.

Measures to reduce the risk of myopathy caused by medicine interactions:
Concomitant administration with itraconazole, ketoconazole, posaconazole, voriconazole, erythromycin, clarithromycin, telithromycin, HIV protease inhibitors, boceprevir, telaprevir and nefazodone is contraindicated (see **CONTRAINDICATIONS**). If treatment with itraconazole, ketoconazole, posaconazole, voriconazole, erythromycin, clarithromycin or telithromycin is unavoidable, therapy with NOVATIN must be suspended during the course of treatment.
The combined use of NOVATIN with gemfibrozil, ciclosporin, or danazol is contraindicated (see **CONTRAINDICATIONS**).

The concomitant use of fusidic acid and NOVATIN increases the risk of myopathy or rhabdomyolysis (see **CONTRAINDICATIONS, WARNINGS AND SPECIAL PRECAUTIONS** and **INTERACTIONS**). NOVATIN should be discontinued throughout the duration of treatment with fusidic acid. Patients should be advised to seek medical attention immediately if they experience symptoms characteristic of myopathy e.g. muscle weakness, pain or tenderness. Treatment with NOVATIN may be re-introduced seven days after the last dose of fusidic acid. In exceptional cases where a patient requires long term treatment with fusidic acid, co-administration with NOVATIN should only be considered on a case by case basis and under close medical supervision.

Myopathy/rhabdomyolysis have been reported with concomitant administration of HMG-CoA reductase inhibitors such as NOVATIN and lipid-modifying doses (≥ 1 g/day) of niacin (nicotinic acid), either of which can cause myopathy when administered alone. The benefits and risks of using NOVATIN concomitantly with lipid-lowering doses of niacin should be carefully considered, and the dose of NOVATIN should generally not exceed 10 mg/day (see **INTERACTIONS,** and **DOSAGE AND DIRECTIONS FOR USE**).
Patients receiving combination therapy of NOVATIN and niacin should be carefully monitored for myopathy and rhabdomyolysis, especially during the first few months of treatment and when the dosage of either medicine is increased.

NOVATIN should be used with caution in combination with medicines known to be moderate CYP3A4 inhibitors e.g. fluconazole, verapamil and diltiazem, since they may increase exposure to simvastatin and consequently the risk of myopathy and rhabdomyolysis (see **INTERACTIONS**). Dosage adjustment of NOVATIN may be necessary (see **DOSAGE AND DIRECTIONS FOR USE**).

The concomitant use of NOVATIN with amiodarone or amlodipine also increases the risk of myopathy and rhabdomyolysis (see **INTERACTIONS**). Caution is advised with the combined use of these medicines and NOVATIN. Dosage adjustment of NOVATIN may be necessary (see **DOSAGE AND DIRECTIONS FOR USE**).

There have been reports of myopathy and rhabdomyolysis with the concomitant use of NOVATIN and colchicine in patients with renal impairment. Caution should be exercised when prescribing this combination. It is recommended that patients are closely monitored (see **INTERACTIONS**).

Hepatic effects:
NOVATIN should be used with caution in patients who consume substantial amounts of alcohol and/or who have a history of liver disease.

It is recommended that liver function tests be performed before the initiation of treatment, and thereafter when clinically indicated. There have been post-marketing reports of fatal and non-fatal hepatic failure in patients taking statins, including simvastatin. If serious liver injury with clinical symptoms and/or hyperbilirubinaemia or jaundice occurs during treatment with NOVATIN, promptly interrupt therapy. If an alternate etiology is not found, do not restart NOVATIN.

Renal impairment:
NOVATIN should be used with caution in patients who have severe renal impairment (see **WARNINGS AND SPECIAL PRECAUTIONS, Myopathy/Rhabdomyolysis**).

Effects on ability to drive and use machines:
NOVATIN has no or negligible influence on the ability to drive and use machines. However, dizziness has been reported with the use of NOVATIN which may influence the patient's ability in this regard (see **SIDE EFFECTS**).

Special precautions relating to the excipients of NOVATIN:
NOVATIN contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency or glucose-galactose malabsorption should not take NOVATIN.

INTERACTIONS:
Myopathy/Rhabdomyolysis caused by medicine interactions:
Strong CYP3A4 inhibitors:
Concomitant administration of medicines that inhibit cytochrome P450 isoenzyme CYP3A4 may result in high plasma levels of simvastatin as in NOVATIN, thus increasing the risk of myopathy and rhabdomyolysis, and is contraindicated. Strong inhibitors of cytochrome P450 isoenzyme CYP3A4 include: itraconazole, ketoconazole, posaconazole, voriconazole, erythromycin, clarithromycin, telithromycin, HIV protease inhibitors, boceprevir, telaprevir and nefazodone.
Combination of these medicines with NOVATIN is contraindicated (see **CONTRAINDICATIONS**). If treatment with itraconazole, ketoconazole, posaconazole, voriconazole, erythromycin, clarithromycin or telithromycin is unavoidable, therapy with NOVATIN must be suspended during the course of treatment.

Gemfibrozil, ciclosporin and danazol:
The combined use of NOVATIN with gemfibrozil, ciclosporin, or danazol is contraindicated (see **CONTRAINDICATIONS**).

Fusidic acid:
The concomitant use of NOVATIN and fusidic acid may increase the risk for myopathy. Increased plasma concentrations of both medicines may occur. There have been reports of rhabdomyolysis, including fatalities. Concomitant use is therefore contraindicated. NOVATIN should be discontinued throughout the duration of treatment with fusidic acid (see **CONTRAINDICATIONS**).

Niacin and other fibrates:
The risk of myopathy is increased when other medicines that cause myopathy, such as fibrates and niacin, are given with NOVATIN.
A maximum dose of 10 mg NOVATIN daily is recommended in patients taking lipid-lowering doses of niacin (nicotinic acid) (see **WARNINGS AND SPECIAL PRECAUTIONS** and **DOSAGE AND DIRECTIONS FOR USE**).

Moderate CYP3A4 inhibitors:
NOVATIN should be used with caution in combination with medicines labelled as moderate CYP3A4 inhibitors e.g. fluconazole, verapamil and diltiazem, which increase exposure to simvastatin and therefore the risk of myopathy and rhabdomyolysis (see **WARNINGS AND SPECIAL PRECAUTIONS**). Dosage adjustment of NOVATIN may be necessary (see **DOSAGE AND DIRECTIONS FOR USE**).

Amlodipine and amiodarone:
Concomitant use of NOVATIN with amiodarone or amlodipine increases the risk of myopathy or rhabdomyolysis (see **WARNINGS AND SPECIAL PRECAUTIONS**). Dosage adjustment of NOVATIN may be necessary (see **DOSAGE AND DIRECTIONS FOR USE**).

Grapefruit juice:
Consumption of large quantities of grapefruit juice (> 1 litre per day), a CYP3A4 inhibitor, while being treated with NOVATIN, increases the exposure to simvastatin and consequently the risk of myopathy and rhabdomyolysis. The use of grapefruit juice is contraindicated during treatment with NOVATIN.

Colchicine:
There have been reports of myopathy and rhabdomyolysis with the concomitant use of NOVATIN and colchicine in patients with renal impairment. It is recommended that patients are closely monitored when receiving this combination (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Digoxin:
NOVATIN may cause increases in digoxin levels. Repeated therapeutic medicine monitoring is recommended for patients on digoxin therapy.

Warfarin:
A possible increase in the anticoagulant effect of warfarin may occur. Patients taking warfarin should have their INR determined before starting NOVATIN therapy. The INR should be monitored frequently enough in the early stages of therapy until stabilised. Once a stable INR has been documented, INR can be monitored at the intervals usually recommended for patients on warfarin. Where there is a dose adjustment of NOVATIN, this procedure should be repeated.

Bile acid sequestrants:
NOVATIN should be taken 1 hour before or 4 hours after cholestyramine. Concurrent use may decrease the bioavailability of NOVATIN.

Rifampicin:
Rifampicin, a potent CYP3A4 inducer, may reduce the efficacy of NOVATIN when taken concomitantly.

PREGNANCY AND LACTATION:
NOVATIN is contraindicated in pregnancy and lactation. The active metabolite of NOVATIN is foetotoxic and teratogenic in rats, and it should therefore not be used in female patients of child-bearing potential.
Women taking NOVATIN should not breastfeed their infants.

DOSAGE AND DIRECTIONS FOR USE:
The patient must follow a cholesterol lowering diet before initiation of, and while on NOVATIN therapy.

Hypercholesterolaemia:
Adults: Initial dose: 10 mg daily as a single dose in the evening.
The dose of NOVATIN should be reduced if LDL-cholesterol levels fall below 1,94 mmol/l, or total plasma cholesterol levels fall below 3,6 mmol/l.

Coronary Heart Disease:
Adults: The dose is 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.

Dose in renal insufficiency:
NOVATIN does not undergo significant renal excretion, therefore modification of dose should not be necessary in patients with mild to moderate renal insufficiency. In patients with severe renal insufficiency NOVATIN therapy should be closely monitored and doses above 10 mg/day should be implemented with caution.

Concomitant therapy:
NOVATIN is effective alone or in combination with bile acid sequestrants. When both medicines are prescribed, NOVATIN should be given 1 hour before or 4 hours after cholestyramine administration (see **INTERACTIONS**).

A maximum daily dose of 10 mg NOVATIN is recommended in patients taking niacin concomitantly (see **WARNINGS AND SPECIAL PRECAUTIONS,** and **INTERACTIONS**).

A maximum daily dose of 10 mg NOVATIN should not be exceeded in patients taking verapamil or diltiazem concomitantly (see **WARNINGS AND SPECIAL PRECAUTIONS,** and **INTERACTIONS**).

A maximum daily dose of 20 mg NOVATIN should not be exceeded in patients taking amiodarone or amlodipine concomitantly (see **WARNINGS AND SPECIAL PRECAUTIONS,** and **INTERACTIONS**).

SIDE EFFECTS:
Endocrine disorders:
Less frequent: Increases HbA1c and fasting glucose levels, diabetes mellitus.

Gastrointestinal disorders:
Less frequent: Constipation, abdominal pain, flatulence, dyspepsia, diarrhoea, nausea, vomiting, pancreatitis, cramps, gastritis.

Respiratory, thoracic and mediastinal disorders:
Frequency unknown: Interstitial lung disease, respiratory infection, bronchitis, sinusitis.

Blood and the lymphatic system disorders:
Less frequent: Anaemia.
Frequency unknown: Neutropenia

Infections and infestations:
Frequency unknown: Urinary tract infections.

Reproductive system and breast disorders:
Frequency unknown: Erectile dysfunction.

Skin and subcutaneous tissue disorders:
Less frequent: Skin rash, pruritus, alopecia, eczema.

Musculoskeletal, connective tissue and bone disorders:
Less frequent: Myopathy, myositis, rhabdomyolysis presenting as muscle pain with elevated creatine phosphokinase and myoglobinuria leading to renal failure, myalgia, muscle cramps, arthralgia.
Frequency unknown: Tendinopathy, cases of immune-mediated necrotising myopathy associated with statin use including NOVATIN, have been reported (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Psychiatric disorders:
Less frequent: Insomnia.
Frequency unknown: Depression, cognitive impairment (memory loss, forgetfulness, amnesia, memory impairment, confusion).

Nervous system disorders:
Less frequent: Headache, paraesthesia, dizziness, peripheral neuropathy.

Cardiac disorders:
Less frequent: Atrial fibrillation.

Immune system disorders:
Less frequent: Hypersensitivity reactions may include anaphylaxis, angio-oedema, lupus-like syndrome, polymyalgia rheumatica, dermatomyositis, vasculitis, purpura, thrombocytopenia, eosinophilia, leukopenia, haemolytic anaemia, positive ANA, increased erythrocyte sedimentation rate, arthritis, arthralgia, urticaria, photosensitivity, fever, chills, flushing, dyspnoea and malaise, toxic epidermal necrolysis, erythema multiforme and Stevens-Johnson syndrome.

Metabolism and nutrition disorders:
Frequency unknown: Mass gain.

General disorders:
Less frequent: Asthenia, fatigue, oedema, swelling.

Investigations:
Less frequent: Marked and persistent increases of serum transaminases (alanine aminotransferase, aspartate aminotransferase, y-glutamyl transpeptidase) and elevated alkaline phosphatase and gamma-glutamyl transpeptidase have been reported. Liver function test abnormalities have generally been mild and transient. Increases in serum creatine kinase (CK) levels, derived from skeletal muscle, have been reported (see **WARNINGS AND SPECIAL PRECAUTIONS**).

Hepato-biliary disorders:
Less frequent: Hepatitis, jaundice, fatal and non-fatal hepatic failure.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(see **SIDE EFFECTS,** and **WARNINGS AND SPECIAL PRECAUTIONS**).
General measures should be adopted and liver function should be monitored.
Treatment is symptomatic and supportive.

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

PRESENTATION:
NOVATIN 5:
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:
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:
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:
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:
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.

STORAGE INSTRUCTIONS:
Store at or below 30 °C.
DO NOT REMOVE BLISTERS FROM THE CARTON UNTIL REQUIRED FOR USE.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
NOVATIN 5: 41/7.5/0381
NOVATIN 10: 41/7.5/0382
NOVATIN 20: 41/7.5/0383
NOVATIN 40: 41/7.5/0384
NOVATIN 80: 41/7.5/0385

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Novagen Pharma (Pty) Ltd
Office 2, 100 Sovereign Drive
Route 21 Corporate Park
Nellmapius Drive
Irene – Pretoria
South Africa

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
Date of registration: 5 October 2007
Date of the most recently revised professional information: 15 April 2020

NAMIBIA Reg. No.: NS2
Novatin 10: 10/7.5/0114
Novatin 20: 10/7.5/0115
Novatin 40: 10/7.5/0116

DETACH BEFORE DISPENSING

PATIENT INFORMATION LEAFLET
NOVATIN

SCHEDULING STATUS:
S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
Novatin 5 Tablet
Novatin 10 Tablet
Novatin 20 Tablet
Novatin 40 Tablet
Novatin 80 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: Each film-coated tablet contains simvastatin 5 mg.
NOVATIN 10: Each film-coated tablet contains simvastatin 10 mg.
NOVATIN 20: Each film-coated tablet contains simvastatin 20 mg.
NOVATIN 40: Each film-coated tablet contains simvastatin 40 mg.
NOVATIN 80: 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 and talc.
Colourants: NOVATIN 5: Iron oxide yellow, titanium dioxide.
NOVATIN 10 & 20: Iron oxide red, iron oxide yellow, titanium dioxide.
NOVATIN 40 & 80: Iron oxide red, titanium dioxide.

NOVATIN contains sugar (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, for:
- raised levels of cholesterol
- coronary heart disease.

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 (statins), 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 affects 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 any of your other medicine is listed above.

Take special care with NOVATIN:
- NOVATIN should not be used by female patients of child bearing potential (i.e. if there is a possibility that you may become pregnant or are planning to have a baby). Discuss this with your doctor.
- 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.
- 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 worsens.
- If you develop unexplained muscle pain, tenderness or weakness, particularly if accompanied by a general feeling of being unwell or fever, report this promptly to your doctor or pharmacist. Your doctor may do blood tests and may tell you to stop taking NOVATIN.
- 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.

Inform your doctor before you start taking NOVATIN, if any of the following conditions apply to you:
- if you are elderly (age ≥ 65 years)
- if you are a female
- if you have thyroid problems
- if you have kidney problems
- if you have a history of hereditary muscle disorders
- if you have previously experienced muscle problems with the use of cholesterol-lowering medicines called statins and fibrates
- if you drink too much alcohol.

Your doctor may do blood tests and determine if you can use NOVATIN.
Your doctor may advise you to stop taking NOVATIN for a few days if you have any of the following conditions:
- if you have a serious infection
- if you have low blood pressure
- if you have metabolic, hormonal or electrolyte problems
- if you have uncontrolled epilepsy
- if you have experienced physical trauma or will be having major surgery.

Tell your doctor if you experience any of the above.
- 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 (when used together with NOVATIN) that 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 kidney or 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:
NOVATIN should not be used if you are planning to get pregnant, while you are pregnant or breastfeeding your baby (see **Do not take NOVATIN**).

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. 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, 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:
In particular, tell your doctor if you are taking any of the following:
- 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: The dose is 10 mg daily as a single dose in the evening.

Coronary Heart Disease:
Adults: The dose is 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 SIDE EFFECTS
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 casualty department at your nearest hospital:
Less frequent:
- Yellowing of the skin and eyes (jaundice), itching, dark-coloured urine or pale coloured stool, weakness, loss of appetite.
- 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NOVATIN. 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:
Less frequent:
- Muscle pain (myalgia), muscle cramps, muscle weakness which may continue even after therapy with NOVATIN has been stopped (myopathy, myositis), breakdown of muscle tissue presenting as muscle pain with elevated creatine phosphokinase (a certain enzyme which indicates 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.
- Headache, damage to the nerves affecting sensation, movement and organ function (peripheral neuropathy), dizziness, pins and needles (paraesthesia).
- 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).
- decrease in the amount of red blood cells or haemoglobin in the blood which are necessary to transport oxygen to the rest of the body (anaemia).
- Skin rash, hair loss (alopecia), inflammation of the skin (eczema), severe itching of skin (pruritus).
- Abnormal heart rhythm (atrial fibrillation).
- 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), 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 indicate that the immune system is attacking the body (positive ANA).
- Fever and/or chills.
- 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-glutamyl transpeptidase), 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).

Frequency unknown:
- 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 number of white blood cells (neutropenia).
- Inflammation and tearing of the tendons (tendinopathy), immune-mediated necrotising myopathy (persistent muscle weakness).
- Abdominal pain, nausea, vomiting, fever.
- Depression, cognitive impairment (memory loss, forgetfulness, memory impairment, amnesia, confusion).

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

Tell your doctor if you notice any of the following:
Less frequent:
- Difficulty sleeping (insomnia).
- Constipation, diarrhoea, passing of wind (flatulence), dyspepsia, cramps, inflammation of the lining of the stomach (gastritis).

Frequency unknown:
- Urinary tract infections.
- Erectile dysfunction which causes problems with sexual intercourse in male patients.
- Mass gain has been reported.

Memory loss and confusion have been reported with NOVATIN use.

If you notice any side effects, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF NOVATIN
Store all medicines out of reach of children.
Store at or below 30 °C.
DO NOT REMOVE BLISTERS FROM THE CARTON UNTIL REQUIRED FOR USE.

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

9. REGISTRATION NUMBER
NOVATIN 5: 41/7.5/0381
NOVATIN 10: 41/7.5/0382
NOVATIN 20: 41/7.5/0383
NOVATIN 40: 41/7.5/0384
NOVATIN 80: 41/7.5/0385

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER
Novagen Pharma (Pty) Ltd
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NAMIBIA Reg. No.: NS2
Novatin 10: 10/7.5/0114
Novatin 20: 10/7.5/0115
Novatin 40: 10/7.5/0116

PROFESSIONELE INLIGTING

SKEDULERINGSTATUS:

S4

NOVAGEN
PHARMA

EIENDOMSNAAM EN DOSERINGSVORM:

Novatin 5 (Tablet)

Novatin 10 (Tablet)

Novatin 20 (Tablet)

Novatin 40 (Tablet)

Novatin 80 (Tablet)

SAMESTELLING:

NOVATIN 5: Elke filmbedekte tablet bevat 5 mg simvastatien.

NOVATIN 10: Elke filmbedekte tablet bevat 10 mg simvastatien.

NOVATIN 20: Elke filmbedekte tablet bevat 20 mg simvastatien.

NOVATIN 40: Elke filmbedekte tablet bevat 40 mg simvastatien.

NOVATIN 80: Elke filmomhulde tablet bevat 80 mg simvastatien.

Hulpstowwe:

Askorbiensuur, butielhidroksie-anisool (antioksidant), sitroensuurmonohidraat, hidroksiepropielsellulose, hipromellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, stysel-voorafgelatiniseer en talk.

Kleurstowwe:

NOVATIN 5: Ysteroksied geel, titaandioksied.

NOVATIN 10 & 20: Ysteroksied rooi, ysteroksied geel, titaandioksied.

NOVATIN 40 & 80: Rooi ysteroksied, titaandioksied.

Bevat suiker (laktosemonohidraat).

FARMAKOLOGIESE KLASSIFIKASIE:

A 7.5 Serumcholesterol verlagers

FARMAKOLOGIESE WERKING:

Simvastatien is 'n cholesterolverlagende middel wat sinteties afkomstig is van 'n fermentasieproduk van *Aspergillus terreus*.

Farmakodinamiese eienskappe:

Na mondelinge inname word simvastatien, 'n onaktiewe laktoon, gehidroliseer tot die ooreenstemmende beta-hidroksiensuur, die aktiewe vorm. Dit is 'n hoofmetaboliet en 'n remmer van 3-hidroksi-3-metielglutariel-koënsiem A (HMG-CoA) reduktase, die ensiem wat die omskakeling van HMG-CoA na mevalonaat kataliseer, 'n vroeë en tempo-beperkende stap in die biosintese van cholesterol. As gevolg hiervan verminder simvastatien totale plasmacholesterol, lae digtheid lipoproteïen (LDL)- en baie lae digtheid lipoproteïen (VLDL)-cholesterolkonsentrasies. Apolipoproteïen B word ook verlaag. Daarbenewens verhoog simvastatien hoëdigtheid lipoproteïen (HDL)-cholesterol matig, en verminder plasma-trigliseriedes veranderlik.

Farmakokinetiese eienskappe:

Absorpsie:

Na 'n mondelinge dosis, word simvastatien goed geabsorbeer en word die plasmakonsentrasies van simvastatien binne 1 tot 2 uur gesien.

Daar is uitgebreide eerste-fase-ekstraksie deur die lewer, met orale biobeskikbaarheid van die aktiewe medisyne of metaboliete minder as 5 %.

Verspreiding:

Meer as 95 % van simvastatien en die beta-hidroksiemetaboliet is aan plasmaproteïene gebind.

Eliminasie:

Simvastatien word hoofsaaklik via die lewer uitgeskei en minder as 13 % van die metaboliete word in die urine uitgeskei.

INDIKASIES:

Hipercholesterolemie:

NOVATIN word aangedui, in kombinasie met dieet, om verhoogde serumcholesterol en LDL-cholesterol in pasiënte met:

- Primêre hiperkolesterolemie,
- Heterosigotiese familiale hipercholesterolemie, of
- Gemengde hiperlipidemie,

wanneer reaksie op dieet of ander nie-farmakologiese maatreëls alleen nie voldoende is nie.

Koronêre hartsiekte:

NOVATIN word aangedui by pasiënte met koronêre hartsiektes en hipercholesterolemie wat nie reageer op dieet nie, om:

- die risiko van totale sterftes te verminder deur koronêre dood te verminder,
- die risiko van nie-fatale miokardiale infarksie te verminder,
- die risiko van miokardiale revaskularisasieprosedures (koronêre arterie omleiding en perkutane transluminale koronêre angioplastie) te verminder, en
- die vordering van koronêre aterosklerose te vertraag.

KONTRAÏNDIKASIES:

Hipersensitiwiteit vir simvastatien, ander HMG-CoA-reduktaseremmers, of enige van die hulpstowwe in NOVATIN.

Akute of chroniese lewersiekte.

Onverklaarbare aanhoudende verhoging van serumtransaminases.

Swangerskap en laktasie (sien **SWANGERSKAP EN LAKTASIE**).

Porfirie: Veiligheid is nie vasgestel nie.

Gelyktydige toediening van sterk CYP3A4-remmers (bv. itrakonasool, ketokonasool, posakonasool, vorikonasool, MIV-protease-remmers, boseprevir, telaprevir, eritromisien, klaritromisien, telitromisien en nefasodoon) (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS,** en **INTERAKSIES**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:

Gebruik by pediatriese pasiënte word nie aanbeveel nie, aangesien veiligheid en doeltreffendheid nie vasgestel is nie.

Diabetes mellitus:

Toenames in HbA1c en vastende serumglukosevlakke is gerapporteer met HMG-CoA-reduktaseremmers, insluitend NOVATIN.

Pasiënte wat die risiko loop om suikersiekte te hê (dws vastende glukose 5,6 tot 6,9 mmol/l, LMI> 30 kg/m^2, verhoogde trigliseriede, hipertensie) moet deeglik gemoniteer word.

Interstisiële longsiekte:

Gevalle van interstisiële longsiekte is gerapporteer met sommige statiene, insluitend NOVATIN, veral met langtermynterapie. Die kenmerke wat voorkom, sluit in dispnee, nie-produktiewe hoes en agteruitgang van die algemene gesondheid (moegheid, gewigsverlies en koors). Indien vermoed word dat 'n pasiënt interstisiële longsiekte ontwikkel het, moet NOVATIN gestaak word.

Miopatie/Rabdomiolise:

Die risiko van miopatie en rabdomiolise hou verband met die dosis.

Hoë plasmavlakke van HMG-CoA-reduktaseremmers, insluitend NOVATIN verhoog die risiko van miopatie. 'n Kreatienkinase (CK) vlak bo 10 maal die boonste limiet van normaal (ULN) by 'n pasiënt, met onverklaarbare simptome (bv. spierpyn, teerheid of swakheid) dui op miopatie. In sommige gevalle kom miopatie voor as rabdomiolise met of sonder akute nierversaking sekondêr tot mioglobinurie. Daar is berig oor sterftes.

Pasiënte moet in kennis gestel word van die verhoogde risiko van miopatie en rabdomiolise met NOVATIN, en moet ingelig word om onverklaarbare spierpyn, teerheid of swakheid onmiddellik te rapporteer. Die behandeling moet onmiddellik gestaak word wanneer hierdie simptome voorkom.

Daar is verslae van immuun-gemedieerde nekrotiserende miopatie (IMNM), wat 'n outo-immuun miopatie is wat verband hou met die gebruik van statiene, insluitend NOVATIN.

Meting van kreatienkinase (CK):

Om akkurate interpretasie van kreatienkinasevlakke (CK) te verseker, moet metings nie geneem word na inspannende oefening, of in die teenwoordigheid van enige ander moontlike oorsaak vir CK-verhoging nie. As CK-vlakke aansienlik verhoog is (> 5 x ULN), moet die vlakke binne 5 tot 7 dae later weer gemeet word om die resultate te bevestig.

Voor behandeling:

Pasiënte wat met NOVATIN begin, of wanneer die dosis NOVATIN verhoog moet word, moet in kennis gestel word van die risiko van miopatie, insluitend rabdomiolise, en moet onmiddellik onverklaarbare spierpyn, teerheid of swakheid rapporteer, veral as dit met malaise of koors gepaard gaan, of as spiertekens en simptome voortduur nadat NOVATIN gestaak is.

NOVATIN-behandeling moet met omsigtigheid begin word by pasiënte met predisponerende faktore vir rabdomiolise. 'n Basiswaarde vir die CK-vlak moet bepaal word voordat die behandeling by die volgende situasies begin word:

- bejaardes (ouderdom ≥ 65 jaar),
- vroulike geslag,
- ernstige nierinkorting,
- onbeheerde hipotireose,
- persoonlike of familiale geskiedenis van oorerflike spierafwykings,
- vorige geskiedenis van spiertoksisiteit met 'n statien of fibraat, en
- alkoholmisbruik.

Waar daar predisponerende faktore bestaan, moet die risiko van behandeling deeglik oorweeg word teenoor die moontlike voordeel. Kliniese monitering word aanbeveel. As 'n pasiënt voorheen 'n spierafwyking op 'n fibraat of statien soos NOVATIN ervaar het, moet die behandeling met 'n ander lid van die klas slegs met omsigtigheid begin word. As CK-vlakke aansienlik verhoog is (> 5 x ULN), moet die behandeling nie begin word nie.

Tydens behandeling:

Meet CK-waardes as spierpyn, swakheid of krampe voorkom tydens behandeling met NOVATIN. Die behandeling moet gestaak word as hierdie vlakke aansienlik verhoog is (> 5 x ULN) as dit gemeet word sonder die inspannende oefening.

Staking van NOVATIN kan oorweeg word as spiersimptome ernstig is en daaglikse ongemak veroorsaak, selfs al is die CK-vlakke <5 x ULN. NOVATIN moet gestaak word as miopatie gediagnoseer of vermoed word.

Die herinstelling van NOVATIN of die instelling van 'n alternatiewe statien teen die laagste dosis, tesame met noukeurige monitering, kan oorweeg word as spiersimptome verdwyn en die CK-vlakke terugkeer na normaal.

Behandeling met NOVATIN 80 hou verband met 'n hoër risiko vir miopatie. Periodieke CK-metings word aanbeveel, aangesien dit nuttig kan wees om subkliniese gevalle van miopatie te identifiseer. Daar is egter geen versekering dat sulke monitering miopatie sal voorkom nie.

Die behandeling met NOVATIN moet tydelik gestaak word in gevalle waar 'n pasiënt geneig is om nierversaking te ontwikkel wat sekondêr is vir rabdomiolise, soos ernstige akute infeksie (bv. sepsis), hipotensie, ernstige metaboliese-, endokriene-, of elektrolietafwykings, onbeheerde aanvalle, ernstige chirurgie of trauma. Daar is 'n verhoogde risiko om nierversaking te ontwikkel as rabdomiolise plaasvind.

Maatreëls om die risiko van miopatie as gevolg van medisyne-interaksies te verminder:

Gelyktydige toediening met itrakonasool, ketokonasool, posakonasool, vorikonasool, eritromisien, klaritromisien, telitromisien, MIV-protease-inhibeerders, boseprevir, telaprevir en nefasodoon is teenaangedui (sien **KONTRAÏNDIKASIES**). As behandeling met itrakonasool, ketokonasool, posakonasool, vorikonasool, eritromisien, klaritromisien of telitromisien onvermydelik is, moet die behandeling met NOVATIN tydens die behandeling opgeskort word.

Die gekombineerde gebruik van NOVATIN met gemfibrosiel, siklosporien of danasool is teenaangedui (sien **KONTRAÏNDIKASIES**).

Die gelyktydige gebruik van fusidiensuur en NOVATIN verhoog die risiko van miopatie of rabdomiolise (sien **KONTRAÏNDIKASIES, WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS** en **INTERAKSIES**). NOVATIN moet tydens die behandeling met fusidiensuur gestaak word. Pasiënte moet aangeraai word om onmiddellik mediese hulp in te win as hulle simptome het wat kenmerkend is van miopatie, bv. spierswakheid, pyn of teerheid. Behandeling met NOVATIN kan weer heringestel word sewe dae na die laaste dosis fusidiensuur. In uitsonderlike gevalle waar 'n pasiënt langdurige behandeling met fusidiensuur benodig, moet die gelyktydige toediening van NOVATIN slegs van geval tot geval, en onder noue mediese toesig oorweeg word.

Miopatie/rabdomiolise is gerapporteer met gelyktydige toediening van HMG-CoA-reduktaseremmers soos NOVATIN en dosisse wat lipiede (≥ 1 g / dag) van niasien (nikotiensuur) verander, wat beide miopatie kan veroorsaak wanneer dit alleen toegedien word. Die voordele en risikos van die gelyktydige gebruik van NOVATIN met lipiedverlagende dosisse niasien moet deeglik oorweeg word, en die dosis NOVATIN moet oor die algemeen nie meer as 10 mg/dag oorskry nie (sien **INTERAKSIES,** en **DOSERING EN GEBRUIKSAANWYSINGS**).

Pasiënte wat kombinasie-terapie van NOVATIN en niasien ontvang, moet noukeurig dopgehou word vir miopatie en rabdomiolise, veral gedurende die eerste paar maande van die behandeling en wanneer die dosering van een van die medisyne verhoog word.

NOVATIN moet met omsigtigheid gebruik word in kombinasie met medisyne wat bekend is as matige CYP3A4-remmers, bv. flukonasool, verapamil en diltiasem, aangesien dit die blootstelling aan simvastatien kan verhoog, en gevolglik die risiko van miopatie en rabdomiolise (sien **INTERAKSIES**). Doseringaanpassing van NOVATIN kan nodig wees (sien **DOSERING EN GEBRUIKSAANWYSINGS**).

Die gelyktydige gebruik van NOVATIN met amiodaroon of amlodipien verhoog ook die risiko van miopatie en rabdomiolise (sien **INTERAKSIES**). Wees versigtig met die gekombineerde gebruik van hierdie medisyne en NOVATIN. Doseringaanpassing van NOVATIN kan nodig wees (sien **DOSERING EN GEBRUIKSAANWYSINGS**).

Daar is verslae van miopatie en rabdomiolise met die gelyktydige gebruik van NOVATIN en kolgisien by pasiënte met nierfunksie. Wees versigtig wanneer hierdie kombinasie voorgeskryf word. Dit word aanbeveel dat pasiënte noukeurig gemoniteer word (sien I**NTERAKSIES**).

Lewereffekte:

NOVATIN moet met omsigtigheid gebruik word by pasiënte wat aansienlike hoeveelhede alkohol gebruik en/of wat 'n geskiedenis van lewersiekte het.

Daar word aanbeveel dat lewerfunksietoetse uitgevoer word voordat die behandeling begin, en daarna, indien dit klinies aangedui word. Daar is na-bemarking verslae van noodlottige en nie-noodlottige lewerversaking by pasiënte wat statiene gebruik, insluitend simvastatien. Indien ernstige lewerbesering met kliniese simptome en/of hiperbilirubinemie of geelsug voorkom tydens behandeling met NOVATIN, moet die behandeling onmiddellik onderbreek word. As 'n alternatiewe etiologie nie gevind word nie, moet NOVATIN nie weer begin word nie.

Nierinkorting:

NOVATIN moet met omsigtigheid gebruik word by pasiënte met ernstige nierinkorting (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS, Miopatie/Rabdomiolise**).

Effekte op die vermoë om bestuur en masjiene te gebruik:

NOVATIN het geen of onbeduidende invloed op die vermoë om masjiene te bestuur en te gebruik nie. Duiseligheid is egter gerapporteer met die gebruik van NOVATIN wat die vermoë van die pasiënt in hierdie verband kan beïnvloed (sien **NEWE-EFFEKTE**).

Spesiale voorsorgmaatreëls met betrekking tot die hulpstowwe van NOVATIN:

NOVATIN bevat laktosemonohidraat. Pasiënte met seldsame oorerflike probleme van galaktose-onverdraagsaamheid bv. galaktosemie, Lapp-laktasetekort of glukose-galaktose wanabsorpsie moenie NOVATIN neem nie.

INTERAKSIES:

Miopatie/Rabdomiolise veroorsaak deur medisyne-interaksies:

Sterk CYP3A4-remmers:

Gelyktydige toediening van medisyne wat sitochroom P450 iso-ensiem CYP3A4 inhibeer, kan lei tot hoë plasmavlakke van simvastatien soos in NOVATIN, wat die risiko vir miopatie en rabdomiolise verhoog, en is teenaangedui. Sterk remmers van sitochroom P450 iso-ensiem CYP3A4 sluit in: itrakonasool, ketokonasool, posakonasool, vorikonasool, eritromisien, klaritromisien, telitromisien, MIV-protease-remmers, boseprevir, telaprevir en nefasodoon.

Die kombinasie van hierdie medisyne met NOVATIN is teenaangedui (sien **KONTRAÏNDIKASIES**). Indien behandeling met itrakonasool, ketokonasool, posakonasool, vorikonasool, eritromisien, klaritromisien of telitromisien onvermydelik is, moet die behandeling met NOVATIN tydens die behandeling opgeskort word.

Gemfibrosiel, siklosporien en danasool:

Die gekombineerde gebruik van NOVATIN met gemfibrosiel, siklosporien of danasool is teenaangedui (sien **KONTRAÏNDIKASIES**).

Fusidiensuur:

Die gelyktydige gebruik van NOVATIN en fusidiensuur kan die risiko vir miopatie verhoog. Verhoogde plasmakonsentrasies van albei medisyne kan voorkom. Daar is verslae van rabdomiolise, insluitend sterftes. Gelyktydige gebruik is dus teenaangedui. NOVATIN moet gestaak word gedurende die duur van die behandeling met fusidiensuur (sien **KONTRAÏNDIKASIES**).

Niasien en ander fibrate:

Die risiko van miopatie word verhoog wanneer ander medisyne wat miopatie veroorsaak, soos fibrate en niasien, saam met NOVATIN gegee word.

'n Maksimum dosis van 10 mg NOVATIN per dag word aanbeveel by pasiënte wat lipiedverlagende dosisse niasien (nikotiensuur) neem (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS** en **DOSERING EN GEBRUIKSAANWYSINGS**).

Matige CYP3A4-remmers:

NOVATIN moet met omsigtigheid gebruik word in kombinasie met medisyne gemerk as matige CYP3A4-remmers, bv. flukonasool, verapamil en diltiasem, wat die blootstelling aan simvastatien verhoog en dus die risiko van miopatie en rabdomiolise (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**). Doseringsaanpassing van NOVATIN kan nodig wees (sien **DOSERING EN GEBRUIKSAANWYSINGS**).

Amlodipien en amiodaroon:

Gelyktydige gebruik van NOVATIN met amiodaroon of amlodipien verhoog die risiko van miopatie of rabdomiolise (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**). Doseringsaanpassing van NOVATIN kan nodig wees (sien **DOSERING EN GEBRUIKSAANWYSINGS**).

Pomelosap:

Die verbruik van groot hoeveelhede pomelosap (> 1 liter per dag), 'n CYP3A4-remmer, verhoog die blootstelling aan simvastatien en gevolglik die risiko van miopatie en rabdomiolise, tydens behandeling met NOVATIN. Die gebruik van pomelosap is teenaangedui tydens behandeling met NOVATIN.

Kolgisien:

Daar is verslae van miopatie en rabdomiolise met die gelyktydige gebruik van NOVATIN en kolgisien by pasiënte met nierfunksie. Dit word aanbeveel dat pasiënte noukeurig dopgehou word wanneer hulle hierdie kombinasie ontvang (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).

Digoksien:

NOVATIN kan digoksienvlakke verhoog. Herhaalde monitering van terapeutiese medisyne word aanbeveel vir pasiënte op digoksienbehandeling.

Warfarien:

'n Moontlike toename in die antikoagulantiewe effek van warfarien kan voorkom. Pasiënte wat warfarien gebruik, moet hul INR bepaal voordat hulle met NOVATIN-behandeling begin. Die INR moet gereeld genoeg gemonitor word in die vroeë stadiums van die behandeling totdat dit gestabiliseer is. Sodra 'n stabiele INR gedokumenteer is, kan INR gemonitor word met die tussenposes wat gewoonlik aanbeveel word vir pasiënte op warfarien. Indien daar 'n dosisaanpassing van NOVATIN is, moet hierdie prosedure herhaal word.

Galsuur sekwestrante:

NOVATIN moet 1 uur voor of 4 uur na cholestiramien geneem word. Gelyktydige gebruik kan die biobeskikbaarheid van NOVATIN verminder.

Rifampisien:

Rifampisien, 'n kragtige CYP3A4-induseerder, kan die effektiwiteit van NOVATIN verlaag wanneer dit gelyktydig geneem word.

SWANGERSKAP EN LAKTASIE:

NOVATIN is teenaangedui tydens swangerskap en laktasie. Die aktiewe metaboliet van NOVATIN is toksies vir die fetus en teratogenies by rotte, en dit moet dus nie gebruik word by vroulike pasiënte met swangerskap-potensiaal nie.

Vroue wat NOVATIN neem, moenie hul babas borsvoed nie.

DOSERING EN GEBRUIKSAANWYSINGS:

Die pasiënt moet 'n cholesterolverlagende dieet volg voordat NOVATIN-behandeling begin word, en tydens.

Hipercholesterolemie:

Volwassenes: Aanvangsdosis: 10 mg per dag as 'n enkel dosis in die aand.

Die dosis NOVATIN moet verlaag word indien LDL-cholesterolvlakke onder 1,94 mmol/l daal, of as die totale plasmacholesterolvlakke onder 3,6 mmol/l daal.

Koronêre Hartsiekte:

Volwassenes: Die dosis is 20 mg/dag as 'n enkel dosis in die aand.

Doseringaanpassings:

Indien nodig, moet die dosis met tussenposes van minstens 4 weke aangepas word, tot 'n maksimum van 80 mg per dag as 'n enkel dosis in die aand. NOVATIN kan saam met etes of op 'n leë maag geneem word.

Dosis by nierontoereikendheid:

NOVATIN word nie beduidend deur die niere uitgeskei nie, daarom behoort dosisaanpassing nie nodig te wees by pasiënte met ligte tot matige nierontoereikendheid nie. By pasiënte met ernstige nierontoereikendheid moet NOVATIN-behandeling noukeurig gemonitor word, en dosisse hoër as 10 mg/dag moet met omsigtigheid geïmplementeer word.

Gelyktydige terapie:

NOVATIN is effektief alleen of in kombinasie met galsuur sekwestrante. Wanneer albei medisyne voorgeskryf word, moet NOVATIN 1 uur voor of 4 uur na toediening van cholestiramien toegedien word (sien **INTERAKSIES**).

'n Maksimum daaglikse dosis van 10 mg NOVATIN word aanbeveel by pasiënte wat gelyktydig niasien gebruik (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS,** en **INTERAKSIES).**

'n Maksimum daaglikse dosis van 10 mg NOVATIN moenie oorskry word by pasiënte wat verapamil of diltiasem gelyktydig gebruik nie (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS** en **INTERAKSIES**).

'n Maksimum daaglikse dosis van 20 mg NOVATIN moenie oorskry word by pasiënte wat amiodaroon of amlodipien gelyktydig gebruik nie (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS** en **INTERAKSIES**).

NEWE-EFFEKTE:

Endokriene afwykings:

Minder gereeld: Verhoog HbA1c en vastende glukosevlakke, diabetes mellitus.

Gastroïntestinale afwykings:

Minder gereeld: Hardlywigheid, buikpyn, winderigheid, dispepsie, diarree, naarheid, braking, pankreatitis, krampe, gastritis.

Respiratoriese-, torakale- en mediastinale afwykings:

Frekwensie onbekend: Interstisiële longsiekte, respiratoriese infeksie, brongitis, sinusitis.

Bloed- en limfstelselafwykings:

Minder gereeld: bloedarmoede.

Frekwensie onbekend: Neutropenie

Infeksies en besmettings:

Frekwensie onbekend: Urienweginfeksies.

Voortplantingstelsel en borsafwykings:

Frekwensie onbekend: Erektiele disfunksie.

Vel- en onderhuidse- weefselafwykings:

Minder gereeld: Veluitslag, pruritus, alopesie, ekseem.

Muskuloskeletale-, bindweefsel-, en beenafwykings

Minder gereeld: Miopatie, miositis, rabdomiolise wat voorkom as spierpyn met verhoogde kreatienfosfokinase en mioglobinurie wat lei tot nierversaking, mialgie, spierkrampe, artralgie en

Frekwensie onbekend: Tendinopatie, gevalle van immuun-gemedieerde nekrotiserende miopatie wat verband hou met statiengebruik, insluitend NOVATIN, is gerapporteer (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).

Psigiatriese afwykings:

Minder gereeld: Slaaploosheid.

Frekwensie onbekend: Depressie, kognitiewe inkorting (geheueverlies, vergeetagtigheid, geheueverlies, geheueverswakking, verwarring).

Senuweestelselafwykings:

Minder gereeld: Hoofpyn, parestesie, duiseligheid, perifere neuropatie.

Hartafwykings:

Minder gereeld: Atriële fibrillasie.

Immuunstelselafwykings:

Minder gereeld: Hipersensitiwiteitsreaksies kan anafilakse, angio-edeem, lupusagtige sindroom, polymialgie rheumatika, dermatomiositis, vaskulitis, purpura, trombositopenie, eosinofilie, leukopenie, hemolitiese anemie, positiewe ANA, verhoogde eritrosiet sedimentasie koers, artritis, artralgie, urtikarie, fotosensitiwiteit, koors, kouekoors, blosing, dispnee en malaise, toksiese epidermale nekrolise, erythema multiforme en Stevens-Johnson-sindroom insluit.

Metabolisme- en voedingsafwykings:

Frekwensie onbekend: Massatoename.

Algemene afwykings:

Minder gereeld: Astenie, moegheid, edeem, swelling.

Ondersoeke:

Minder gereeld: Gemerkte en aanhoudende toenames in serumtransaminases (alanienaminotransferase, aspartaataminotransferase, y-glutamiel-transpeptidase) en verhoogde alkaliese fosfatase en gamma-glutamiel-transpeptidase is gerapporteer. Afwykings in lewerfunksietoetse was oor die algemeen matig en kortstondig. Toenames in serumkreatienkinase (CK) vlakke, afgelei van skeletspiere, is gerapporteer (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).

Hepato-biliêre afwykings:

Minder gereeld: Hepatitis, geelsug, fatale en nie-fatale lewerversaking.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING:

(sien **NEWE-EFFEKTE** en **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).

Algemene maatreëls moet getref word en lewerfunksie moet gemonitor word.

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

NOVATIN 5: Geel gekleurde, ronde, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '15' aan die ander kant gedruk.

NOVATIN 10: Ligpienk gekleurde, ronde, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '01' aan die ander kant gedruk.

NOVATIN 20: Ligpienk gekleurde, ronde, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '02' aan die ander kant gedruk.

NOVATIN 40: Pienk gekleurde, ronde, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '03' aan die ander kant gedruk.

NOVATIN 80: Pienk gekleurde, kapsuulvormige, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '04' aan die ander kant gedruk.

AANBIEDING:

NOVATIN 5:

1. PVC/ACLAR

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

NOVATIN 10:

1. PVC/ACLAR

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stolpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

NOVATIN 20:

1. PVC/ACLAR

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineerd met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stolpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 GSM PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stolpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

NOVATIN 40:

1. PVC/ACLAR

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

NOVATIN 80:

1. PVC/ACLAR

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette. Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit onduersigtige 250 mikron PVC-film, gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette. Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

BEWARINGINSTRUKSIES:

Bêre teen of benede 30 °C.

MOENIE DIE STULPSTROKE UIT DIE KARTON VERWYDER TOTDAT DIT NODIG IS VIR GEBRUIK NIE. HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

NOVATIN 5: 41/7.5/0381

NOVATIN 10: 41/7.5/0382

NOVATIN 20: 41/7.5/0383

NOVATIN 40: 41/7.5/0384

NOVATIN 80: 41/7.5/0385

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:

Novagen Pharma (Pty) Ltd

Kantoor 2, Sovereignrylaan 100

Route 21 Corporate Park

Nellmapiusrylaan

Irene - Pretoria

Suid-Afrika

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING:

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Datum van die mees onlangse hersiende professionele inligting: 15 April 2020

NAMIBIË Reg. No.: NS2
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Novatin 20: 10/7.5/0115
Novatin 40: 10/7.5/0116

P1527433

DETACH BEFORE DISPENSING

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:

S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

Novatin 5 Tablet

Novatin 10 Tablet

Novatin 20 Tablet

Novatin 40 Tablet

Novatin 80 Tablet

Lees die hele pamflet aandagtig deur voordat u NOVATIN begin gebruik.

- Bewaar hierdie pamflet. U moet dit miskien weer lees.

- As u verdere vrae het, vra asseblief u dokter of apteker.

- NOVATIN is persoonlik aan u voorgeskryf en u moet u medisyne nie met ander mense deel nie. Dit kan hulle benadeel, selfs al is hulle simptome dieselfde as joune.

1. WAT NOVATIN BEVAT

Die aktiewe bestanddeel is simvastatien.

NOVATIN 5: Elke filmbedekte tablet bevat 5 mg simvastatien.

NOVATIN 10: Elke filmbedekte tablet bevat 10 mg simvastatien.

NOVATIN 20: Elke filmbedekte tablet bevat 20 mg simvastatien.

NOVATIN 40: Elke filmbedekte tablet bevat 40 mg simvastatien.

NOVATIN 80: Elke filmbedekte tablet bevat 80 mg simvastatien.

Die ander bestanddele is askorbiensuur, butielhidroksianisool, sitroensuur monohidraat, hidroksipropielsellulose, hipromellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, stysel-voorafgelatiniseer en talk.

Kleurstowwe: NOVATIN 5: Ysteroksied geel, titaandioksied.

NOVATIN 10 & 20: Ysteroksied rooi, ysteroksied geel, titaandioksied.

NOVATIN 40 & 80: Rooi ysteroksied, titaandioksied.

NOVATIN bevat suiker (laktosemonohidraat).

2. WAT NOVATIN VOOR GEBRUIK WORD

NOVATIN bevat simvastatien wat die cholesterolvlakke in u bloed verlaag deur die produksie van cholesterol te voorkom.

NOVATIN word gebruik, in kombinasie met 'n beheerde dieet, vir:

- verhoogde vlakke van cholesterol
- koronêre hartsiekte.

3. VOORDAT U NOVATIN NEEM

Moenie NOVATIN neem:

- As u hipersensitief (allergies) is vir simvastatien, ander medisyne wat in dieselfde klas as simvastatien (statiene) is, of enige van die bestanddele van NOVATIN.
- As u akute of chroniese lewersiekte het.
- As u onverklaarbare aanhoudende verhoging van serumtransaminases (lewerensieme) ervaar.
- As u swanger is of borsvoed.
- As u aan 'n oorerflike afwyking genaamd porfirie ly, wat die produksie van sekere ensieme in u liggaam beïnvloed en gevolglik u vermoë om sekere medisyne te metaboliseer, benadeel. Die veiligheid van NOVATIN is nie vasgestel by pasiënte met porfirie nie.
- As u een van die volgende medisyne gebruik: itrakonasool, ketokonasool, posakonasool, vorikonasool, MIV-protease-inhibeerders, boseprevir, telaprevir, eritromisien, klaritromisien, telitromisien, nefasodoon, gemfibrosiel, siklosporien of danasool.

Vra u dokter indien u nie seker is of enige van u ander medisyne hierbo gelys word nie.

Wees veral versigtig met NOVATIN:

- NOVATIN moenie deur vroulike pasiënte met swangerskap potensiaal gebruik word nie (dit wil sê as daar die moontlikheid bestaan dat u swanger kan raak of van plan is om 'n baba te hê). Bespreek dit met u dokter.
- Kinders moenie NOVATIN gebruik nie, aangesien die veiligheid en effektiwiteit van NOVATIN nie by kinders vasgestel is nie.
- Verhogings in bloedsuikervlakke is gerapporteer met die gebruik van NOVATIN.
- Daar is verslae van interstisiële longsiekte, 'n longtoestand wat die ruimte rondom die lugsakke van die longe beïnvloed, by pasiënte wat NOVATIN gebruik. Stel u dokter dadelik in kennis as u asemhalingsprobleme ervaar, 'n droë hoes ontwikkel, of as u algemene gesondheid versleg.
- As u onverklaarbare spierpyn, teerheid of swakheid ontwikkel, veral as u 'n algemene gevoel van ongesteldheid of koors het, moet u dit dadelik aan u dokter of apteker rapporteer. U dokter kan bloedtoetse doen, en kan u aanraai om op te hou met NOVATIN.
- As u dokter gesê het dat u moet stop met die gebruik van NOVATIN as gevolg van spierprobleme, moet u dadelik u dokter in kennis stel as die simptome nie verdwyn nie.

Stel u dokter in kennis voordat u NOVATIN begin gebruik, indien een van die volgende voorwaardes op u van toepassing is:

- as u ouer is (ouderdom ≥ 65 jaar)
- as u 'n vrou is
- as u skildklierprobleme het
- as u nierprobleme het
- as u oorerflike spierafwykings het
- as u voorheen spierprobleme ondervind het met die gebruik van cholesterolverlagende medisyne genaamd statiene en fibrate
- as u te veel alkohol drink.

U dokter kan bloedtoetse doen en bepaal of u NOVATIN kan gebruik.

U dokter kan u aanraai om NOVATIN vir 'n paar dae te stop as u een van die volgende toestande het:

- as u 'n ernstige infeksie het
- as u lae bloeddruk het
- as u metaboliese, hormonale of elektrolietprobleme het
- as u ongekontroleerde epilepsie het
- as u fisiese trauma ervaar het, of 'n groot operasie gaan ondergaan.

Vertel u dokter as u een van die bogenoemde ervaar.

- Dit is baie belangrik dat u, indien u reeds ander medisyne gebruik, u dokter daarvan in kennis moet stel voordat u NOVATIN begin gebruik. Daar is sekere medisyne wat saam met NOVATIN gebruik word, die vlakke van NOVATIN in u bloed verhoog, en gevolglik die risiko van ernstige newe-effekte wat u spiere (miopatie) en niere (rabdomiolise) insluit. Raadpleeg "**Neem van ander medisyne saam met NOVATIN**" hieronder vir die lys van medisyne.
- As u aan nier- of lewersiekte ly, en u aansienlike hoeveelhede alkohol gebruik en/of 'n geskiedenis van lewersiekte het.
- Daar is verslae van ernstige lewerprobleme by pasiënte wat NOVATIN gebruik. Pasiënte moet dadelik hul gesondheidswerker in kennis stel as hulle die volgende simptome het: ongewone moegheid of swakheid; eetlus verloor; pyn in die boonste maag; donkerkleurige urine; of vergeling van die vel of die wit van die oë.

Neem van NOVATIN saam met kos en vloeistof:

Moenie pomelosap drink as u NOVATIN gebruik nie. Groot hoeveelhede pomelosap (bv. meer as 1 liter per dag) kan die vlakke van NOVATIN in u bloed verhoog en gevolglik die risiko van spier- en nierprobleme verhoog. Verwys na "**Neem spesiale sorg met NOVATIN**" hierbo vir meer inligting.

Swangerskap en borsvoeding:

NOVATIN moenie gebruik word as u van plan is om swanger te raak, of terwyl u swanger is of u baba borsvoed nie (sien "**Moenie NOVATIN neem nie**").

As u swanger is of u baba borsvoed, raadpleeg u dokter, apteker of ander gesondheidswerker vir advies voordat u NOVATIN neem.

Bestuur en gebruik van masjinerie:

NOVATIN kan u duiselig laat voel, wat u vermoë om te bestuur en masjiene te hanteer kan beïnvloed.

Belangrike inligting oor sommige van die bestanddele van NOVATIN:

NOVATIN bevat 'n suiker wat bekend staan as laktosemonohidraat. U moenie NOVATIN neem as u aan oorerflike siektes ly, wat u sensitief of onverdraagsaam vir laktose maak nie. Vertel u dokter of gesondheidsorgverskaffer indien u aan so 'n afwyking ly.

Neem van ander medisyne saam met NOVATIN:

NOVATIN is in wisselwerking met itrakonasool, ketokonasool, posakonasool, vorikonasool, MIV-protease-inhibeerders, boseprevir, telaprevir, eritromisien, klaritromisien, telitromisien, nefasodoon, gemfibrosiel, siklosporien en danasool.

NOVATIN moet 1 uur voor of 4 uur na cholestiramien geneem word. Raadpleeg asseblief u dokter as u immuunonderdrukkers, fibrate of niasien gebruik.

Benewens die bogenoemde medisyne:

Vertel u dokter veral as u een van die volgende neem:

- warfarien (om bloedklonte te voorkom)
- fenofibraat ('n cholesterolverlagende middel)
- niasien ('n cholesterolverlagende middel)
- rifampisien (antibiotika wat gebruik word vir tuberkulose/TB)
- flukonasool (antiswam medisyne)
- fusidiensuur (antibiotika)
- digoksien of amiodaroon (gebruik vir hartsiektes)
- verapamil, diltiasem of amlodipien (gebruik vir hoë bloeddruk en hartsiektes)
- kolgisien (gebruik vir jig).

U moet ook aan enige dokter wat nuwe medisyne vir u voorskryf, vertel dat u NOVATIN gebruik.

Vertel altyd u gesondheidswerker as u enige ander medisyne gebruik.

(Dit sluit komplementêre of tradisionele medisyne in.)

4. HOE OM NOVATIN TE NEEM

Neem NOVATIN altyd presies soos u dokter u beveel het. Raadpleeg u dokter of apteker indien u nie seker is nie. Vertel u dokter of apteker as u die indruk het dat die effek van NOVATIN te sterk of te swak is. U moet 'n cholesterolverlagende dieet volg voordat u NOVATIN-behandeling begin, en terwyl u dit ondergaan. Bespreek dit met u gesondheidswerker.

Hipercholesterolemie:

Volwassenes: Die dosis is 10 mg per dag as 'n enkel dosis in die aand.

Koronêre hartsiekte:

Volwassenes: Die dosis is 20 mg/dag as 'n enkel dosis in die aand.

Doseringsaanpassings:

Indien nodig, moet die dosis met tussenposes van minstens 4 weke aangepas word, tot 'n maksimum van 80 mg per dag as 'n enkel dosis in die aand.

NOVATIN kan saam met etes of op 'n leë maag geneem word.

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie. Dit kan hulle benadeel.

As u meer NOVATIN neem as wat u moet:

In geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As u vergeet om NOVATIN te neem:

Moenie 'n ekstra dosis neem nie; neem net u normale hoeveelheid NOVATIN op die gewone tyd die volgende dag.

Moenie 'n dubbele dosis neem om vir die vergete dosisse op te maak nie.

5. MOONTLIKE NEWE-EFFEKTE

NOVATIN kan newe-effekte hê. Nie alle newe-effekte wat vir NOVATIN gerapporteer is, is in hierdie pamflet ingesluit nie. Raadpleeg u dokter, apteker of ander gesondheidswerker vir advies indien u algemene gesondheid vererger of as u enige newe-effekte ervaar tydens die gebruik van NOVATIN.

As een van die volgende gebeur, moet u stop om NOVATIN te neem, en dit onmiddellik aan u dokter vertel of na die ongevalle-afdeling by u naaste hospitaal gaan:

Minder gereeld:

- Vergeling van die vel en oë (geelsug), jeuk, donkerkleurige urine of ligkleurige stoelgang, swakheid, verlies aan eetlus.
- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat moeilike asemhaling of sluk kan veroorsaak (anafilakse, angio-edeem).
- Jeukerige, rooi veluitslag, bekend as korwe (urtikarie), blosing.

Hierdie is alles baie ernstige newe-effekte. As u dit het, het u moontlik 'n ernstige allergiese reaksie op NOVATIN gehad. U benodig moontlik dringende mediese hulp of hospitalisasie.

Vertel dadelik u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal as u een van die volgende opmerk:

Minder gereeld:

- Spierpyn (mialgie), spierkrampe, spierswakheid wat kan voortduur selfs nadat die behandeling met NOVATIN gestaak is (miopatie, miositis), afbreek van spierweefsel wat voorkom as spierpyn met verhoogde kreatienfosfokinase ('n sekere ensiem wat dui op spierafbreking) en mioglobinurie (bruin gekleurde urine as gevolg van spierproteïen in die urine) wat lei tot renale/nierversaking (rabdomiolise). Spierprobleme kan baie ernstig wees en kan lei tot nierbeskadiging, en ook die dood as dit nie behandel word nie.
- Hoofpyn, skade aan die senuwees wat die sensasie, beweging en orgaanfunksie (perifere neuropatie) beïnvloed, duiseligheid, spelde en naalde (parestesie).
- Toename in HbA1c, 'n bloedkomponent wat gebruik word om bloedglukose/suikervlakke te bepaal, toename in vastende glukose/suikervlakke, metaboliese afwyking wat hoë bloedglukose/suikervlakke veroorsaak (diabetes mellitus).
- Afname in die hoeveelheid rooibloedselle of hemoglobien in die bloed wat nodig is om suurstof na die res van die liggaam te vervoer (bloedarmoede).
- Veluitslag, haarverlies (alopesie), ontsteking van die vel (ekseem), erge jeuk in die vel (pruritus).
- Abnormale hartritme (atriële fibrillasie).
- Blasies wat op die slymvliese van die mond, keel, oë, anus en geslagsdele ontstaan, afskilfering van die vel (erythema multiforme, Stevens - Johnson-sindroom, toksiese epidermale nekrolise).
- Lupusagtige sindroom wat simptome soos veluitslag, sensitiwiteit vir die son (fotosensitiwiteit), konstante gewrigspyn (artritis of artralgie), long- en nierprobleme kan insluit.
- Kortasem, moegheid (tamheid), algemene gevoel van ongemak of ongesteldheid (dispnee en ongesteldheid, hemolitiese bloedarmoede).
- Pyn en styfheid in die nek, skouers en heupe (polimialgia rheumatica).
- Veluitbarstings en swelling (dermatomiositis).
- Abnormale kneusing, rooi/pers verkleuring op die vel, neusbloeding, bloeiende tandvleis (vaskulitis, purpura, trombositopenie).
- Veranderings in rooi en witbloedselle (verhoogde eritrosiet-sedimentasiekoers, eosinofilie, leukopenie).
- Bloedtoetse toon die teenwoordigheid van auto-teenliggaampies aan, wat toon dat die immuunstelsel die liggaam aanval (positiewe ANA).
- Koors en/of kouekoors.
- Fisiese swakheid (astenie), swelling veroorsaak deur vloeistofretensie (edeem).
- Opgemerkte en aanhoudende toenames van lewerensieme in die bloed (serumtransaminases en verhoogde alkaliese fosfatase en gamma-glutamiel-transpeptidase), hoewel, die veranderinge in lewerfunksie was oor die algemeen matig en kortstondig; verhoogde bloedvlakke van kreatienkinase (CK), 'n ensiem wat gebruik word om vas te stel of daar spierbeskadiging was.

Frekwensie onbekend:

- Longtoestand wat die ruimte rondom die lugsakke van die longe beïnvloed (interstisiële longsiekte), lugweginfeksie, ontsteking van die slymvliese in die longe (brongitis), ontsteking van die nasale sinusse (sinusitis).
- Afname in die aantal witbloedselle (neutropenie).
- Inflammasie en skeur van die tendons (tendinopatie), immuun-gemedieerde nekrotiserende miopatie (aanhoudende spierswakheid).
- Buikpyn, naarheid, braking, koors.
- Depressie, kognitiewe inkorting (geheueverlies, vergeetagtigheid, geheueverswakking, geheueverlies, verwarring).

Hierdie is alles baie ernstige newe-effekte. U benodig moontlik dringende mediese hulp of hospitalisasie.

Vertel u dokter as u een van die volgende opmerk:

Minder gereeld:

- Probleme met slaap (slaaploosheid).
- Hardlywigheid, diarree, winde (winderigheid), dispepsie, krampe, ontsteking van die maagwand (gastritis).

Frekwensie onbekend:

- Urienweginfeksies.
- Erektiele disfunksie wat probleme met seksuele omgang by manlike pasiënte veroorsaak.
- Gewigstoename is aangemeld.

Geheueverlies en verwarring is gerapporteer met die gebruik van NOVATIN.

As u enige newe-effekte opmerk, moet u asseblief u dokter of apteker daarvan in kennis stel.

6. BERGING EN WEGDOENING VAN NOVATIN

Berg alle medisyne buite bereik van kinders.

Berg by of onder 30 °C.

MOENIE DIE STULPSTROKE UIT DIE KARTON VERWYDER TOT BENODIG VIR GEBRUIK NIE.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in die riool of rioolstelsels (bv. toilette) weggooi nie.

7. AANBIEDING VAN NOVATIN

NOVATIN 5:

1. PVC/ACLAR

Tablette is verpak in wit ondeursigtige 250 mikron PVC- film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

NOVATIN 10:

1. PVC/ACLAR

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

NOVATIN 20:

1. PVC/ACLAR

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

NOVATIN 40:

1. PVC/ACLAR

Tablette word verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

NOVATIN 80:

1. PVC/ACLAR

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte: 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC-film gelamineer met 50 mikron aclar en 25 mikron gedrukte aluminiumfoelie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

2. PVC/PE/PVdC

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 10 tablette.

Verpakkingsgrootte 30's: Elke karton bevat 3 stulpstroke van 10 tablette elk.

Tablette is verpak in wit ondeursigtige 250 mikron PVC film gelamineer met 25 mikron PE, bedek met 60 gsm PVdC en 25 mikron gedrukte aluminiumfolie. Elke stulpstrook bevat 14 tablette.

Verpakkingsgrootte: 28's: Elke karton bevat 2 stulpstroke van 14 tablette elk.

8. IDENTIFIKASIE VAN NOVATIN

NOVATIN 5: Geel gekleurde, ronde, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '15' aan die ander kant gedruk.

NOVATIN 10: Ligpienk gekleurde, ronde, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '01' aan die ander kant gedruk.

NOVATIN 20: Ligpienk gekleurde, ronde, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '02' aan die ander kant gedruk.

NOVATIN 40: Pienk gekleurde, ronde, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '03' aan die ander kant gedruk.

NOVATIN 80: Pienk gekleurde, kapsuulvormige, bikonvekse, filmbedekte tablette, met 'A' aan die een kant en '04' aan die ander kant gedruk.

9. REGISTRASIENOMMER

NOVATIN 5: 41/7.5/0381

NOVATIN 10: 41/7.5/0382

NOVATIN 20: 41/7.5/0383

NOVATIN 40: 41/7.5/0384

NOVATIN 80: 41/7.5/0385

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER

Novagen Pharma (Pty) Ltd

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Route 21 Corporate Park

Nellmapiusrylaan

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