NOVARTIS

LESCOL ® XL

(fluvastatin sodium)

Prolonged release tablets 80 mg

Basic Succinct Statement

CODE: BSS RD 14 Mar 16; APPR 25 Aug 16

This material is only meant for Healthcare Professionals

LESCOL® XL

Important note: Before prescribing, consult full prescribing information.

Presentation: Fluvastatin sodium. Lescol® XL prolonged release tablets containing the equivalent of 80 mg fluvastatin free acid.

Indications Lescol XL is indicated as an adjunct to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B) and triglycerides (TG) levels and for the increase of high-density lipoprotein cholesterol (HDL-C) in patients with primary hypercholesterolemia and mixed dyslipidemia (Fredrickson Types IIa and IIb).

Prior to initiating therapy with Fluvastatin, secondary causes of hypercholesterolaemia (e.g. poorly controlled diabetus mellitus, hypothyroidism, nephrotic syndrome, dysproteinaemias, obstructive liver disease, other drug therapy, alcoholism) should be identified and treated.

Lescol XL is indicated to reduce the rate of progression of atherosclerosis in patients with coronary artery disease and mild to moderate elevations of cholesterol as part of a treatment strategy to lower total and LDL cholesterol to target levels.

Lescol XL is also indicated in patients with coronary heart disease for the secondary prevention of coronary events after percutaneous coronary intervention.

Dosage: ♦Dyslipidaemia and slowing of the progression of coronary atherosclerosis: Prior to initiating Lescol, the patient should be placed on a standard cholesterol-lowering diet; dietary therapy should be continued during treatment. The recommended starting dose is 40 mg (1 capsule Lescol 40 mg once daily) or 80 mg (1 capsule Lescol 40 mg twice daily or 1 tablet Lescol XL 80 mg at any time of the day) for adults. 20 mg (1 capsule Lescol 20 mg) may be adequate in mild cases.

♦Secondary prevention of major adverse cardiac events in adults with CHD after coronary transcatheter therapy: the recommended daily dose is 80 mg.

Contraindications: ♦Hypersensitivity to fluvastatin or any of the excipients. ♦In patients with active liver disease or unexplained, persistent elevations in serum transaminases. ♦During pregnancy and breast-feeding.

Warnings/Precautions: ♦Post marketing cases of fatal and non-fatal hepatic failures have been reported with some statins including Lescol XL. Although a causal relationship with Lescol XL treatment has not been determined, patients should be advised to report any potential symptoms or signs of hepatic failure, and treatment discontinuation should be considered. Liver function should be monitored. ♦Caution is required in patients with a history of liver disease or heavy alcohol consumption, with unexplained diffuse myalgias, muscle pain/tenderness/weakness, and marked elevation of creatine kinase (CK) values. ♦ There have been rare reports of immune-mediated necrotizing myopathy (IMNM), an autoimmune myopathy, associated with statin use. ♦In patients with pre-disposing factors for rhabdomyolysis, the CK-level should be measured prior to treatment initiation. ♦Caution with co-administration of fibrates, nicotinic acid , erythromycin and ciclosporin. ♦Use of statins might have effects on glucose metabolism. Increased glycosylated hemoglobin (HbA1C) and/or fasting plasma glucose levels were observed in patients treated with statins. New onset of diabetes mellitus was also reported in patients with risk factors for diabetes mellitus.

Interactions: Fibrates; nicotinic acid; fluconazole; ciclosporin; bile acid-sequestrants; rifampicin; phenytoin; oral anticoagulants; glibenclamide; colchicines.

Adverse reactions: ♦**Common:** Dyspepsia, abdominal pain, nausea, headache, insomnia. ♦**Rare:** Hypersensitivity reactions (mainly rash and urticaria), myalgia, muscular weakness, myopathy, blood creatine phosphokinase increased, blood transaminases increased. ♦**Very rare:** Thrombocytopenia, anaphylactic reaction, paresthesia, dysesthesia, hypoesthesia, vasculitis, hepatitis, other skin reactions (e.g. eczema, dermatitis, bullous exanthema), face edema, angioedema, rhabdomyolysis, myositis, lupus erythematosus-like reactions, pancreatitis. ♦**Unknown:** Erectile dysfunction, immune-mediated necrotizing myopathy (IMNM). ♦**Post-marketing:** cognitive impairment, increase in HbA1c and fasting glucose