



# 15 million

Americans now taking a statin drug<sup>1</sup>



## **69%**

Of older patients reported missing doses of a pill or capsule due to difficulty swallowing<sup>2</sup>



#### 1

Statin medication available in liquid form





# He still can't fight down a pill.

# New FloLipid<sup>™</sup> (simvastatin) is the first and only liquid statin.

- Bioequivalent to Zocor® (simvastatin)
- Available in 20 mg/5 mL and 40 mg/5 mL formulations
- No refrigeration required
- May be easier for patients with swallowing issues
- Smooth liquid/syrup consistency and texture
- Pleasant strawberry flavor

To learn more about FloLipid, please visit **salernopharma.com** 

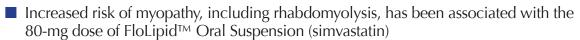


### **IMPORTANT SAFETY INFORMATION**

- FloLipid Oral Suspension (simvastatin) is contraindicated:
  - With concomitant administration of strong CYP3A4 inhibitors, gemfibrozil, cyclosporine, or danazol
  - In patients with a known hypersensitivity to any component of the medication
  - In patients with active liver disease or unexplained persistent elevations in hepatic transaminase levels
  - In women who are or may become pregnant or who are nursing

For more information, please see the full Prescribing Information and Patient Information for FloLipid Oral Suspension.

# **IMPORTANT SAFETY INFORMATION (continued)**





- Risk increases with concomitant use of certain medicines
- Predisposing factors include advanced age (≥65), female gender, uncontrolled hypothyroidism, and renal impairment
- Patients should be advised to report promptly any unexplained and/or persistent muscle pain, tenderness, or weakness
- FloLipid Oral Suspension therapy should be discontinued immediately if myopathy is diagnosed or suspected
- Monitoring of creatine phosphokinase levels is merited in patients with a history of renal insufficiency
- FloLipid Oral Suspension should be used with caution in patients taking other lipid-lowering drugs (other fibrates, ≥1 g/day of niacin, or lomitapide), amiodarone, dronedarone, verapamil, diltiazem, amlodipine, ranolazine, or colchicine. Lower doses of FloLipid Oral Suspension are recommended in these patients
- Persistent increases in serum transaminases have occurred in some patients who received simvastatin in clinical studies
  - It is recommended that liver function tests be performed before the initiation of treatment with FloLipid Oral Suspension, and thereafter when clinically indicated
- Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including simvastatin
- The most commonly reported adverse reactions in controlled clinical trials of simvastatin were upper respiratory infection, headache, abdominal pain, constipation, and nausea

### **INDICATIONS**

- FloLipid Oral Suspension (simvastatin) is an HMG-CoA reductase inhibitor indicated as an adjunct to diet to:
  - Reduce the risk of total mortality by reducing coronary heart disease (CHD) deaths and to reduce the risk of non-fatal myocardial infarction, stroke, and the need for coronary and non-coronary revascularization procedures in patients at high risk of coronary events
  - Reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B
     (Apo B), and triglycerides (TG) and increase high-density lipoprotein cholesterol (HDL-C) in patients
     with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia
  - Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and very-low-density lipoprotein cholesterol (VLDL-C) in patients with primary dysbetalipoproteinemia
  - Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia
  - Reduce elevated total-C, LDL-C, and Apo B in boys and postmenarchal girls 10 to 17 years of age with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy
- **Limitations of Use:** FloLipid Oral Suspension has not been studied in Fredrickson types I and V hyperlipidemia

For more information, please see the full Prescribing Information and Patient Information for FloLipid Oral Suspension.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.



Strachan I, Greener M. Medication-related swallowing difficulties may be more common than we realise. *Pharmacy in Practice*. 2005;15(9):411-414.
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