



**Tough enough to battle his way back from 2 wars and a stroke.**



**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™ (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](http://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)



- Increased risk of myopathy, including rhabdomyolysis, has been associated with the 80-mg dose of FloLipid™ Oral Suspension (simvastatin)
  - Risk increases with concomitant use of certain medicines
  - Predisposing factors include advanced age ( $\geq 65$ ), 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,  $\geq 1$  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.**

1. IMS data

2. 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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