

## Proposed Important Safety Information (ISI) Copy for FloLipid Oral Suspension

### HCP

#### 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

#### 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
- Increased risk of myopathy, including rhabdomyolysis, has been associated with the 80-mg dose of FLOLIPID Oral Suspension
  - 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

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

## **Consumer**

### **INDICATIONS**

- FloLipid Oral Suspension is a prescription medicine that is used along with diet to lower the amount of cholesterol and fatty substances called triglycerides in your blood
- FloLipid can be used to:
  - Lower high cholesterol or triglyceride levels in the blood when diet, exercise, and weight loss are not enough
  - Lower high cholesterol levels that are hereditary (close members of your family also have high cholesterol levels). FloLipid may be taken at the same time as other cholesterol-lowering medicines
  - Lower your risk of coronary heart disease (CHD) if you have diabetes, have had a stroke, or have other blood vessel diseases

### **IMPORTANT SAFETY INFORMATION**

- FloLipid Oral Suspension is not for everyone. You should not take FloLipid if you:
  - Have had an allergic reaction to any of the ingredients of this medicine
  - Have liver problems
  - Are breast-feeding, pregnant, or may become pregnant
  - Are taking certain drugs
- Before taking FloLipid, tell your doctor if you:
  - Have an existing medical condition, including allergies
  - Drink large amounts of alcohol
  - Have a history of liver disease, kidney problems, or severe lung disease
- While taking FloLipid, tell your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. On rare occasions, serious muscle problems have been associated with the use of FloLipid, including muscle breakdown resulting in kidney damage
- Tell your doctor about all of the medicines you take, including those bought without a prescription. This may help to avoid serious drug interactions

- Your doctor should do a blood test before you start taking FloLipid and if you have any symptoms of liver problems while taking FloLipid. Your doctor may also want you to have blood tests after you start taking FloLipid. Because elevated blood sugar levels have been reported with drugs like FloLipid, your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes
- The most common side effects with FloLipid are upper respiratory infection, headache, abdominal pain, constipation, and nausea. If you should have any side effects while taking FloLipid, tell your doctor

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