



Dear Doctor:

As part of our approved physician network, you may see one or more of our members as patients. The International Association of EMTs and Paramedics, an affiliate of The National Association of Government Employees, is committed to providing physicians, as well as our members and their families, with the most current information on prescription medications. As part of this commitment, for your convenience, we are pleased to provide you with this information on lipid-lowering therapy. This important information relates to LIPITOR[®] (atorvastatin calcium) Tablets.

Offering our members and your patients effective and versatile therapeutic options, such as LIPITOR, is reinforced by the following data from the American Heart Association (AHA).¹

- 1 in 3 adults has some form of CVD
- About every 26 seconds, an American will suffer a coronary event
- Stroke is a leading cause of serious, long-term disability in the United States
- Every 45 seconds, someone will suffer a stroke

These statistics can have a meaningful impact on our member population.

LIPITOR is available to our members through their prescription plans. IAEP leadership stands behind LIPITOR as the lipid-lowering agent of choice when it is prescribed by a physician. This confidence in LIPITOR is based on its proven efficacy and is supported by its vast clinical experience of more than 15 years.²

Additionally, LIPITOR has been studied in more than 400 ongoing and completed clinical trials, including more than 80,000 patients worldwide.²

LIPITOR is the only statin with more than 144 million patient-years of experience.³

Furthermore, IAEP recognizes that not all statins are the same—only LIPITOR delivers these 3 important statin benefits:

- >50% potent mean LDL-C reductions at the 40-mg starting dose^{*}
- Proven CV outcomes
 - 47% reduction in the risk of nonfatal MI, with a mean 40-mg dose, in patients with CHD compared with usual care (ALLIANCE; $P=.0002$)^{4**†}
 - 48% reduction in the risk of stroke, with LIPITOR 10 mg, in patients with type 2 diabetes and ≥ 1 risk factor but without CHD compared with placebo (CARDS; $P=.016$)^{5‡}
 - 25% reduction in the risk of stroke, with LIPITOR 80 mg in patients with CHD compared with LIPITOR 10 mg (TNT; $P=.02$)^{6§}
 - 41% reduction in the risk of hospitalization for CHF with LIPITOR 80 mg in patients with CHD and prior CHF compared with LIPITOR 10 mg (TNT-CHF post hoc analysis; $P=.008$)⁷⁻
- Established safety profile
 - No dose-dependent myalgia across the dose range[¶]
 - No clinically significant INR increase with warfarin^{¶#}
 - No dose adjustment required in patients with renal dysfunction[¶]
 - Low incidence of persistent ALT/AST elevations^{¶***}

Due to increased risk of myopathy seen with LIPITOR and other statins, lower starting doses of LIPITOR should be considered when administered concomitantly with fibric acid derivatives, erythromycin, clarithromycin, ritonavir/saquinavir, ritonavir/lopinavir, immunosuppressive drugs, azole antifungals, or niacin; and physicians should carefully monitor patients for signs or symptoms of myopathy early during therapy and when titrating dose of either drug.

It is recommended that liver function tests be performed prior to and 12 weeks following both the initiation of therapy and any elevation of dose, and periodically thereafter. If ALT or AST values $>3 \times$ ULN persist, dose reduction or withdrawal is recommended.

In a post hoc analysis of the SPARCL study in 4731 patients without CHD who had a stroke or TIA within the preceding 6 months, a higher incidence of hemorrhagic stroke was seen in the LIPITOR 80-mg group compared with placebo. Patients with hemorrhagic stroke on study entry appeared to be at increased risk of hemorrhagic stroke.

In clinical trials, the most common adverse events were constipation, flatulence, dyspepsia, and abdominal pain.

Please see full prescribing information enclosed. This letter and the information provided were supported by Pfizer Inc.

*LIPITOR 40 mg may be a starting dose for patients who require an LDL-C reduction $>45\%$.

[†]In ALLIANCE, LIPITOR 10 mg/day, titrated to LDL-C <80 mg/dL or until a maximum LIPITOR dose of 80 mg was achieved, provided a 17% reduction vs usual care in risk of the primary end point: major CV events ($P<.001$). ALLIANCE (N=2442) compared outcomes in hyperlipidemia CHD patients. The primary end point was time to first occurrence of CV events, defined as cardiac death, nonfatal MI, resuscitated cardiac arrest, cardiac revascularization, or unstable angina requiring hospitalization.⁴

[‡]In CARDS, LIPITOR 10 mg provided a 37% reduction vs placebo in risk of the primary end point of a major CV event ($P=.001$). CARDS (N=2838) assessed the effect of LIPITOR 10 mg vs placebo in non-CHD patients with type 2 diabetes, elevated cholesterol (LDL-C ≤ 160 mg/dL, TG ≤ 600 mg/dL), and ≥ 1 of the following risk factors: retinopathy, albuminuria, hypertension, or current smoking. The primary end point was time to first occurrence of a major CV event, defined as a composite of acute CHD events (ie, MI including silent MI, unstable angina, acute fatal CHD, resuscitated cardiac arrest), coronary revascularization, or stroke.⁹

[§]In TNT, LIPITOR 80 mg provided a 22% reduction vs LIPITOR 10 mg in risk of the primary end point: major CV events ($P<.001$). TNT (N=10,001) assessed the efficacy and safety of lowering LDL-C <100 mg/dL in CHD patients with mean LDL-C <130 mg/dL who were randomized to receive either LIPITOR 80 mg or LIPITOR 10 mg.⁶ The primary end point was time to first occurrence of a major CV event, defined as fatal CHD, nonfatal non-procedure-related MI, resuscitated cardiac arrest, or fatal or nonfatal stroke.

-In a prespecified end point of TNT, LIPITOR 80 mg provided an overall 26% reduction in the risk of hospitalization for CHF (N=10,001; $P=.01$).⁶ The data cited were based on a post hoc analysis of patients with prior CHF (n=781).⁷

[†]According to product labeling.

[#]Warfarin is one of the most common drugs involved with concomitant interactions.¹⁰

**Persistent ALT/AST were $>3 \times$ ULN twice within 4 to 10 days.



In addition, in patients with clinically evident CHD, LIPITOR is indicated to reduce the risk of:

- Nonfatal MI
- Stroke
- Revascularization procedures
- Angina
- Hospitalization for CHF

As you know, not every patient responds to every drug in the same manner; switching statins may mean starting over and can lead to disruption of care. Patients whose statin therapy has been switched may be less compliant and less persistent.⁸

When appropriate, we ask that you please consider an agent like LIPITOR for our members with high cholesterol with or without clinically evident CHD.

We recognize that a number of patient-specific variables, which are not available to us, must be taken into account. These findings and suggestions are provided as supplemental information for your consideration. We recognize that you, as the patient's health care provider, are best qualified to choose the most appropriate medications for your patients.

We hope that you find this information useful, and that you will join us in our commitment to ensuring that our members receive quality treatment.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Matthew Ray'.

Director

IMPORTANT INFORMATION:

LIPITOR is indicated to reduce the risk of myocardial infarction (MI), revascularization procedures, angina, and stroke in adult patients with multiple risk factors but without clinically evident coronary heart disease (CHD); to reduce the risk of MI and stroke in patients with type 2 diabetes and without clinically evident CHD, but with multiple risk factors; to reduce the risk of nonfatal MI, fatal and nonfatal stroke, revascularization procedures, hospitalization for congestive heart failure (CHF), and angina in adult patients with clinically evident CHD.

LIPITOR, as an adjunct to diet, is also indicated to reduce elevated TC, LDL-C, apo B, and TG levels; and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia.

LIPITOR is contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases; in women who are or may become pregnant or who are nursing; in patients with hypersensitivity to any component of this medication.

Rare cases of rhabdomyolysis have been reported with LIPITOR and other statins. With any statin, tell patients to promptly report muscle pain, tenderness, or weakness. Discontinue drug if myopathy is suspected, if creatine phosphokinase (CPK) levels rise markedly, or if the patient has risk factors for rhabdomyolysis.

References:

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8. Thiebaud P, Patel BV, Nichol MB, Berenbeim DM. The effect of switching on compliance and persistence: the case of statin treatment. *Am J Manag Care*. 2005;11:670-674.
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