April, 2018

IMPORTANT DRUG WARNING

Subject: Important Drug Adverse Events Associated with Use of CARNITOR® (levocarnitine):

- Hypersensitivity
- Anaphylaxis
- Allergic Reactions

Dear Health Care Provider:

The purpose of this letter is to inform you of important safety Information regarding CARNITOR® (levocarnitine), a prescription product that is a carrier molecule in the transport of long-chain fatty acids across the inner mitochondrial membrane. CARNITOR® (levocarnitine) is indicated in the treatment of primary systemic carnitine deficiency. CARNITOR® (levocarnitine) is also indicated for acute and chronic treatment of patients with an inborn error of metabolism which results in secondary carnitine deficiency.

Drug Adverse Events Associated with Use of:

CARNITOR® (levocarnitine) Injection 1 g per 5 ml vial

Adverse events such as allergic reactions, hypersensitivity and Anaphylaxis have been reported with the use CARNITOR® (levocarnitine):

Prescriber Action

It is recommended that prescribers be aware of the risk for hypersensitivity and anaphylaxis and monitor their patients appropriately. If a severe hypersensitivity reaction occurs, discontinue CARNITOR® (levocarnitine) treatment and initiate appropriate medical treatment. Consider the risks and benefits of re-administering CARNITOR® (levocarnitine) to individual patients following a severe reaction. If the decision is made to re-administer the product, monitor patients for a reoccurrence of signs and symptoms of a severe hypersensitivity reaction.

Reporting Adverse Events

Health Care Providers and patients are encouraged to report adverse events in patients taking CARNITOR® (levocarnitine) to Leadiant Biosciences, Inc. at drugsafety@Leadiant.com or via FAX (301) 354-5346. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

This letter is not intended as a complete description of the benefits and risks related to the use of CARNITOR® (levocarnitine). Please refer to the enclosed full prescribing information.
If you have any questions or concerns about the information contained in this letter or the safe and effective use of CARNITOR® (levocarnitine) please feel free to contact our medical information service at 1 (866) 634-2765 or leadiant@tmacmail.com

Sincerely

Joseph M. Wiley, MD, FAAP
Vice President, Medical Affairs, Drug Safety and Pharmacovigilance

Enclosure: CARNITOR® (levocarnitine) Full Prescribing Information