

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](mailto: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](http://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](mailto:leadiant@tmacmail.com)

Sincerely

Joseph M. Wiley, MD, FAAP

Vice President, Medical Affairs, Drug Safety and Pharmacovigilance

Enclosure: [CARNITOR® \(levocarnitine\) Full Prescribing Information](#)