

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) Tablets (330mg)**

**CARNITOR® (levocarnitine) Oral Solution (1 g per 10 ml multidose)**

**CARNITOR® SF (levocarnitine) Sugar-Free Oral Solution (1 g per 10 ml multidose)**

**Levocarnitine- Generic Tablets (330mg)**

**Levocarnitine -Generic Oral Solution (1 g per 10 ml multidose)**

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 use of CARNITOR and instruct patients to seek medical attention if they experience symptoms suggestive of a hypersensitivity reaction.

### **Reporting Adverse Events**

Health Care Providers and patients are encouraged to report adverse events in patients taking CARNITOR® (levocarnitine) to Lediand Biosciences, Inc. at [drugsafety@Lediand.com](mailto:drugsafety@Lediand.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](#)