



Notice to Healthcare Professionals

May 25, 2016

Dear Healthcare Professional,

Subject: Shortage of Sigma-Tau Pharmaceuticals Inc. Canadian labelled CARNITOR (levocarnitine) Tablets (330mg, 90 tablets/carton) (DIN: 02144328) and temporary replacement with US labelled CARNITOR (levocarnitine) Tablets (330mg, 90 tablets/carton).

Sigma-Tau Pharmaceuticals Inc. is experiencing a shortage of Canadian labelled CARNITOR (levocarnitine) Tablets (330mg, 90 tablets/carton) due to manufacturing issues. This shortage is expected to begin in May 2016 and will continue until the fall of 2016.

After May 27, 2016, physicians and hospitals may request special access to US labelled CARNITOR Tablets through Health Canada's Special Access Programme (SAP). The programme will consider requests on a *case-by-case* basis for limited supplies to bridge this gap.

Patients currently on CARNITOR Tablets can be switched to CARNITOR Oral Solution (1g/10mL, 118 mL bottle). A carton of Carnitor tablets (330mg/tablet) contains 90 tablets for a total amount of about 30g of active ingredient (levocarnitine). The same amount of active ingredient can be obtained and appropriately administered using three bottles of CARNITOR Oral Solution (1g/10mL). One 330 mg tablet can be replaced by 3.3 mL (about $\frac{3}{4}$ teaspoon) of Oral Solution. CARNITOR Oral Solution does contain sucrose. Only those patients unable to tolerate CARNITOR Oral Solution will be eligible for access to the US labelled CARNITOR Tablets.

Requests may be initiated by individual practitioners for the care of one or more patients on a case-by-case basis. Requests should specify all emergency uses of the drug and outline when and where alternatives have failed or are considered inappropriate. Requests should be faxed to SAP in the usual manner.

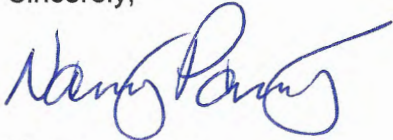
Every effort is made by SAP to process requests within 24 hours of receipt. If the request is complete and the clinical rationale is deemed acceptable (i.e. aligned with Canadian Product Monograph), a Letter of Authorization will be issued to the manufacturer and copied to the requesting practitioner. The product authorized under the SAP will be US labelled CARNITOR Tablets with Lot #140587 with an expiration date of 3/31/2019.

- Due to shortage of Canadian labelled CARNITOR (levocarnitine) Tablets (330mg, 90 tablets/carton), physicians may request special access to US labelled CARNITOR (levocarnitine) Tablets (330mg, 90 tablets/carton) via Health Canada's Special Access Programme (SAP).
- The US product and the Canadian product are similar in terms of strength and packaging but the labels are different. Both the US Prescribing Information and the Canadian Product Monograph will be available.
- Physicians may request access on a case-by-case basis by submitting a **SAP Form A** request. For more information about this process, please consult the following web site or call the SAP main line:

<http://www.healthcanada.gc.ca/sap>
(613) 941-2108 (telephone)
(613) 941-3194 (fax)

Sigma-Tau Pharmaceuticals Inc. is working as quickly as possible to rectify the situation and appreciates your patience and understanding during this inconvenience to you and your patients. You will be notified as soon as the normal commercial supply becomes available. If you have any questions regarding the SAP process, please contact the SAP main line as listed above. Questions regarding CARNITOR (levocarnitine) Tablets (330mg, 90 tablets/carton) can be directed to: Sigma-Tau Pharmaceuticals Inc. at **1-877-666-9454**.

Sincerely,



Nancy Parsons

Sigma-Tau Pharmaceuticals Inc.