
From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, August 29, 2017 8:47 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - Wockhardt

This is to inform you of a "Product Recall" at the Retail Level involving Wockhardt's following product:

- Enalapril Maleate Tablets USP 2.5 mg and 5 mg.
- Lot No. DR10821 (for 2.5 mg) and Lot No. DR10635 & DR10636 (for 5 mg).

This product is used for treating hypertension. See enclosed product label and product leaflet for your reference.

This recall has been initiated because at 3 Months Accelerated Stability Testing (40°C/75% RH), an Out of Specification was reported for related compound test for the Lot No. DRI 0635 on November 16, 2016. During further OOS investigation and impact analysis at Wockhardt India, Lot No. DR10636 & DR10821 were discovered with increased impurity levels as compared to typical long-term stability results. Hence the firm has decided to recall all the three (3) lots of this product.

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.

Product	Lot No.	Pack Size	NDC Number	Expiry Date	Distribution Dates (Beginning and End Date)
Enalapril Maleate Tablets USP, 2.5 mg	DR10821	1000 Tablets Container	64679-923-03	August 2019 (08/2019)	01/19/2017 -06/08/2017
Enalapril Maleate Tablets USP, 5 mg	DR10635	1000 Tablets Container	64679-924-03	May 2019 (05/2019)	04/11/2017-05/18/2017
Enalapril Maleate Tablets USP, 5 mg	DR10636	1000 Tablets Container	64679-924-03	May 2019 (05/2019)	11/11/2016-06/29/2017