### Company Announcement



# Endo Pharmaceuticals Issues Voluntary Nationwide Recall for Two Lots of Robaxin® 750mg Tablets 100 Count Bottle Packs Due to Incorrect Daily Dosing Information on Label

### For Immediate Release

September 28, 2018

### Contact

**Consumers**

Inmar
robaxin@inmar.com (mailto:robaxin@inmar.com)
1-866-391-0620

### Announcement

View Product Photos

Endo International plc (NASDAQ: ENDP) today announced that one of its operating companies, Endo Pharmaceuticals Inc., is voluntarily recalling two lots of Robaxin® (methocarbamol tablets, USP) 750mg Tablets 100 Count Bottle pack to the consumer level. The products have been found to have incorrect daily dosing information on the label due to a labeling error which misstates the daily dose as "two to four tablets four times daily" rather than the correct dosage of "two tablets three times daily." (see picture below for location of incorrect text).

Patients who follow the directions on the bottle may experience significant drowsiness or dizziness which would put them at risk of falls or an overdose which could result in seizures, coma, or death. To date, Endo Pharmaceuticals Inc. has not received any reports of adverse events related to this recall.

Robaxin® 750mg Tablets contain the active ingredient methocarbamol and are indicated as an adjunct therapy to rest, physical therapy and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. Robaxin® 750mg Tablets are packed in bottles of 100 tablets with package labeling featuring the product name, strength, lot number, expiry date and the National Drug Code number NDC 52244-449-10.

The recall includes the following product lots:

- Robaxin® 750mg, 100 Count Bottle pack, Lot 216702P1, Expiration Date: September 2020; and
- Robaxin® 750mg, 100 Count Bottle pack, Lot 220409P1, Expiration Date: January 2021.

No other lots of Robaxin® are affected by this market action.

Robaxin® 750mg 100 Count Bottle packs were distributed by wholesale distributors to retail pharmacies.

Endo Pharmaceuticals Inc. is notifying distributors and retailers in writing through Inmar, Inc. Inmar is arranging for return of all recalled products.

Distributors and retailers that have product which is being recalled should stop distributing and dispensing and return to the place of purchase.

Consumers in possession of any unused prescribed Robaxin® 750mg product bearing lot numbers 216702P1 or 220409P1 should discontinue use of the product and return the unused product by following the instructions below:

- **Please contact Inmar at 1-866-391-0620, Monday through Friday (9am to 5pm ET) or email robaxin@inmar.com (mailto:robaxin@inmar.com) for the following:**
  - **Product Return**
    - **Upon contacting Inmar and indicating you have unused product, please expect Return Authorization labels and Shipping instructions.**
  - **Product Reimbursement**
    - **Upon contacting Inmar, please be prepared to share proof of purchase.**
      - **Proof of purchase can be sent to robaxin@inmar.com (mailto:robaxin@inmar.com) or 635 Vine St.Winston Salem, NC 27101-Attention Recall Department, Robaxin Recall.**

**Distributors, retailers and consumers with questions regarding this recall can contact Inmar by telephone at 1-866-391-0620 during the following hours: Monday through Friday (9am to 5pm ET) or by email at *robaxin@inmar.com (mailto:robaxin@inmar.com)*.** Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then

complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This Product Recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

Endo Pharmaceuticals Inc. takes this issue seriously and works to achieve high quality standards for all of its products and packaging. If you have any questions, please call 1-800-462-ENDO (3636), between the hours of 8:00 a.m. to 8:00 p.m. ET Monday through Thursday and 8:00 a.m. to 6:00 p.m. ET on Friday. Additional information regarding this recall can be found at **http://www.endo.com/endopharma/our-products (http://www.endo.com/endopharma/our-products)**.

###