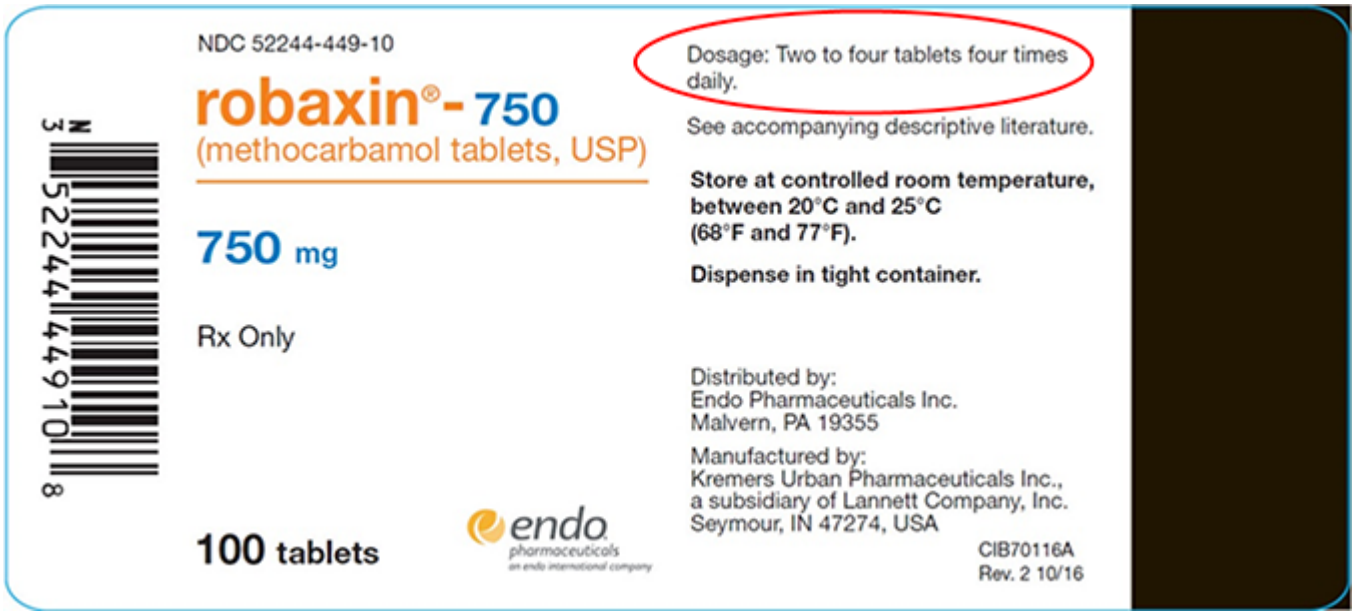
# Endo Pharmaceuticals Issues Voluntary Nationwide Recall for Two Lots of Robaxin® 750mg Tablets 100 Count Bottle Packs Due to Incorrect Daily Dosing Information on Label

September 28, 2018

DUBLIN, Sept. 28, 2018 /PRNewswire/ -- 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.comfor***

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

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form or 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.

**About Endo International plc**

Endo International plc (NASDAQ: ENDP) is a global specialty pharmaceutical company focused on improving patients' lives while creating shareholder value. Endo develops, manufactures, markets and distributes quality branded and generic pharmaceutical products as well as over-the-counter medications through its operating companies. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

**Cautionary Note Regarding Forward-Looking Statements**

Certain information in this press release may contain certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and any applicable Canadian securities legislation. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect our current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and in Canada on the System for Electronic Data Analysis and Retrieval and as otherwise enumerated herein or therein, could individually or in the aggregate affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in the forward-looking statements or from historical results. The forward-looking statements in this press release are qualified by these risk factors. Endo assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

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SOURCE Endo International plc

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