

**NDA 19-384 NOROXIN<sup>®</sup> (NORFLOXACIN) Tablets**

Class of Product: Fluoroquinolone

Merck & Co., Inc.

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**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

I. **GOAL:** The goal of the REMS is to inform patients of the serious risks associated with the use of Noroxin<sup>®</sup>, particularly the increased risks of tendonitis and tendon rupture.

II. **REMS ELEMENTS:**

**A. Medication Guide (MG)**

i. A Medication Guide will be dispensed with each Noroxin<sup>®</sup> prescription in compliance with 21 CFR 208.24. The Medication Guide will replace the current Patient Product Information (PPI) for this product. Merck & Co., Inc. will provide adequate copies of the Medication Guide to pharmacies to ensure its availability for dispensing to each patient who receives a prescription for Noroxin<sup>®</sup> from that pharmacy. The label of each container or package of Noroxin<sup>®</sup> will include a prominent instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed. Merck & Co, Inc. will also make additional printed Medication Guides available upon request from pharmacists via order forms that will accompany Medication Guide deliveries, a toll-free number for the Merck National Service Center, and the Merck website.

ii. Please see the appended Medication Guide.

**B. Communication Plan**

i. The REMS for Noroxin<sup>®</sup> does not include a Communication Plan.

**C. Elements to Assure Safe Use**

i. The REMS for Noroxin<sup>®</sup> does not include Elements to Assure Safe Use.

**D. Implementation System**

i. Because the REMS for Noroxin<sup>®</sup> does not include Elements to Assure Safe Use, an implementation system is not required.

**E. Timetable for Submission of Assessments of the REMS**

i. 1<sup>st</sup> assessment submission: *Insert date 18 months after approval.*

ii. 2<sup>nd</sup> assessment submission: *Insert date by 3 years after approval.*

iii. 3<sup>rd</sup> assessment submission: *Insert date in the 7th year after approval.*

III. **INFORMATION NEEDED FOR ASSESSMENTS:**

A. Please refer to REMS Supporting Document.