NDA 20-634, NDA 20-635, NDA 21-721
Levaquin® (levofloxacin) Tablets, Injection, Oral Solution

Class Of Product: Fluoroquinolones

Ortho McNeil-Janssen Pharmaceutical, Inc.
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Raritan, NJ 08869-0602

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1. GOAL

The goal of the LEVAQUIN® REMS is to inform patients of the serious risks associated with the use of LEVAQUIN, particularly the increased risks of tendonitis and tendon rupture.

2. REMS ELEMENTS

2.1 Medication Guide

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI), will include a supply of package inserts that include the Medication Guides to the wholesaler with each shipment of LEVAQUIN in accordance with 21 CFR 208.24.

OMJPI will separately supply additional copies of the pre-printed Medication Guides to all retail and hospital pharmacies to ensure that every patient who is dispensed a prescription will have access to the LEVAQUIN Medication Guide. These additional shipments will occur at least biannually.

Please see the appended Medication Guide.

2.2 Communication Plan

The REMS for LEVAQUIN does not include a Communication Plan.

2.3 Elements To Assure Safe Use

The proposed REMS for LEVAQUIN does not include Elements to Assure Safe Use.

2.4 Implementation System

The proposed REMS for LEVAQUIN does not include Elements to Assure Safe Use, therefore, a description of the system to monitor and evaluate implementation the Elements of Safe Use is not applicable.

2.5 Timetable for Submission of Assessments

REMS Assessments will be submitted to the FDA in accordance with the following schedule:

Assessment Submission	Date	Timing Relative to Approval
1st Assessment	dd mmm yyyy	18 months after approval
2nd Assessment	dd mmm yyyy	3 years after approval
3rd Assessment	dd mmm yyyy	7 years after approval