

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

Class Of Product: Fluoroquinolones

Ortho McNeil-Janssen Pharmaceutical, Inc.
Route 202, P.O. Box 300
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.