

NDA 19-847, NDA 19-857, NDA 20-780, NDA 19-537, NDA 21-473
Cipro® (ciprofloxacin)
Tablets, Oral Suspension, I.V. Solution, Extended Release Tablets
Class of Product: Fluoroquinolones
Bayer Healthcare Pharmaceuticals Inc.
P.O. Box 1000
Montville, NJ 07045-1000
1-888-842-2937

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of the REMS is to inform patients of the serious risk associated with the use of Cipro®, particularly the increased risk of tendinitis and tendon rupture.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide (MG) will be dispensed with each Cipro® prescription.

Pursuant to 21 CFR 208.24, the MG will be made available in sufficient numbers to US Cipro® distributors. US distributors will provide the MG with every pharmacy shelf carton of Cipro® to ensure its availability for dispensing to patients who are dispensed Cipro®. The label of each container or package of Cipro® will include a prominent instruction to authorized dispensers to provide a MG to each patient to whom the drug is dispensed, and state how the MG is provided.

B. Communication Plan

The REMS for Cipro® does not include a Communication Plan.

C. Elements to Assure Safe Use

The REMS for Cipro® does not include Elements to Assure Safe Use.

D. Implementation System

Because this REMS for Cipro® does not include Elements to Assure Safe Use, an implementation system is not required.

III. Assessment of REMS

Results that have become available from the individual assessment activities as well as corrective actions and other pertinent information will be summarized in REMS Assessment Reports that will be submitted to FDA at 18 months, 3 years, and 7 years after the REMS is approved.