

NDA 21-744/S-012  
Page 4

**NDA: 21-744**  
**Proquin® XR**  
**(Ciprofloxacin Hydrochloride)**  
**Extended-Release Tablets, 500 mg**  
**Class of Product: Fluoroquinolones**  
Depomed Inc.  
1360 O'Brien Drive  
Menlo Park, CA. 94025-1436  
Hayley Welton,  
Associate Director,  
Regulatory Affairs  
[hwelton@depomed.com](mailto:hwelton@depomed.com)  
Phone: 650-462-5900, ext. 302

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

### **1. GOAL:**

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

### **2. REMS ELEMENTS:**

#### **A. Medication Guide (MG)**

Depomed shall comply with the requirements of 21 CFR Part 208.24 for distributing and dispensing Medication Guides. Sponsors will provide adequate copies of the Medication Guide to ensure its availability for dispensing to each patient who receives a prescription for Proquin XR. The following statement "ENCLOSED MEDICATION GUIDE IS TO BE DISPENSED TO PATIENT," has been added on the outer carton label to notify dispensers that a Medication Guide is to be dispensed with the product.

The Medication Guide is currently available at these resource points:

1. Proquin XR packaging to pharmacists contain instructions to provide a Medication Guide to each patient who is given a prescription for Proquin XR.
2. Proquin XR information for prescribing healthcare providers contains instructions to provide a Medication Guide to each patient who is given a sample of Proquin XR.
3. An online downloadable copy is currently available on the Depomed product Proquin XR website [www.proquinxr.com](http://www.proquinxr.com)

NDA 21-744/S-012  
Page 5

Please refer to the FDA approved **Proquin XR Medication Guide** (Effective date: October 2008) appended at the end of this proposed REMS.

#### **B. Communication Plan**

The REMS for Proquin XR does not include a communication plan.

#### **C. Elements to Assure Safe Use**

The REMS for Proquin XR does not include elements to assure safe use.

#### **D. Implementation System**

Because the REMS for Proquin XR do not include elements to assure safe use therefore an implementation plan is not required.

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

Depomed will submit a REMS assessment to FDA at 18 months, 3 years, and 7 years following the approval of this REMS.