NDA 21-158 Factive® (gemifloxacin mesylate)

Class of Product: Fluoroquinolone antibiotic
Oscient Phannaceuticals
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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 Factive®, particularly the increased risks of tendonitis and tendon rupture.

II. REMS ELEMENTS:

A. Medication Guide

In compliance with 21 CFR 208.24, Oscient will institute the following measures:

- Each Factive package will contain a tear-off Medication Guide from the Package Insert (PI). The FDA approved Package Insert including the Medication Guide dated October 2008 is provided in Appendix I.
- Oscient will provide adequate copies of the tear-off Medication Guide from the PI with every pharmacy shelf carton to ensure its availability for dispensing to each patient who receives a prescription for Factive. The label of each container or package of Factive will include a prominent instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and state how the Medication Guide is provided.
- The Factive single Professional Sample, 5-dose, and 7-dose cartons shall include the following statement "Enclosed Medication Guide is to be dispensed to patients". This statement will instruct the authorized dispenser to provide a Medication Guide to each patient to whom the drug is dispensed.
- The revised PI including the Medication Guide will be available via sales representatives, the product website, or through the Sponsor toll-free medical communication line.
- Until such time as the Medication Guide is available as a tear-off from the PI included in each Factive package, Oscient will take the following measures to ensure that the FDA approved PI including the Medication Guide is available for distribution to patients by authorized prescribers and dispensers:

    - For all existing product at the retail pharmacy level, a fax blast will be sent to retail pharmacies detailing that there is a revised PI including the Medication Guide that needs to accompany all dispensed Factive prescriptions. The fax will detail how the pharmacy can obtain the new labeling documents, either by downloading and printing them from the product website or by calling a 1-800 number and requesting a shipment to the pharmacy.
    - For samples at the physician's office, a fax blast will be sent to all physicians that distribute Factive samples detailing that there is a revised PI including the Medication

Guide that needs to accompany all dispensed Factive® samples. The fax will detail how the physician can obtain the new labeling documents, either by downloading and printing them from the product website or by calling a 1-800 number and requesting a shipment to the office.

- Factive sales representatives will be notified via email of the revised PI including the Medication Guide. The email will inform them that when they leave Factive samples at the physician's office, they need to ensure that a revised PI including the Medication Guide accompanies each sample.

B. Communication Plan

The REMS for Factive does not include a Communication Plan.

C. Elements to Assure Safe Use

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

D. Implementation System

This REMS does not include Elements to Assure Safe Use and as such, implementation system is not required.

E. Timetable for Submission of Assessments of the REMS

Oscient Pharmaceutical will submit REMS Assessments to FDA at 18 months, 3 years, and 7 years following the approval of the REMS.