

NDA 17-854 REGLAN[®] tablets (metoclopramide tablets, USP)

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of this REMS is to minimize the risk of tardive dyskinesia associated with the long term use of REGLAN[®] tablets (metoclopramide tablets, USP).

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each REGLAN tablet prescription. REGLAN tablets are supplied as 5mg and 10 mg tablets (supplied in bottles of 100 tablets).

In accordance with 21 CFR 208.24, Alaven will package a sufficient number of Medication Guides with each container of drug product to ensure that a Medication Guide is available for distribution to patients. Four Medication Guides will be packaged within the plastic overwrapping for each bottle. A tear pad of Medication Guides will also be provided to all US pharmacies that dispense REGLAN tablets.

The Medication Guide will be available for distribution to all patients with each prescription that is dispensed. Additional Medication Guides can be accessed from

www.alavenpharm.com. Therefore, Alaven Pharmaceutical (the Sponsor) has met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide. A reminder to provide the Medication Guide each time REGLAN tablets are dispensed will be printed on the bottle.

The Medication Guide is attached to this document as Appendix A.

B. Communication Plan

This REMS for REGLAN tablets does not include a Communication Plan.

C. Elements to Assure Safe Use

This REMS for REGLAN tablets can be approved without Elements to Assure Safe Use.

D. Implementation System

Because this REMS for REGLAN tablets can be approved without Elements to Assure Safe Use, an implementation system is not required.

E. Timetable for Submission of Assessments

REMS Assessments will be submitted to the FDA 18 months, 3 years and 7 years after approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission for that assessment.