

ANDA 74-703 Metoclopramide Oral Solution, USP 5 mg/ 5 mL

Morton Grove Pharmaceuticals, Inc.

Attention: Ralph Hodosh, PhD

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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 Metoclopramide Oral Solution.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each prescription for Metoclopramide Oral Solution. The product is supplied as a 5 mg/ 5 mL solution in pint bottles (473 mL).

In accordance with 21 CFR 208.24, Morton Grove will package a sufficient number of Medication Guides with each 16 oz. container of Metoclopramide Oral Solution USP, 5 mg/5mL so that each patient receiving a prescription can receive a copy of the Medication Guide. Morton Grove will attach two copies of the Medication Guide to each bottle so that they will be available for distribution with each prescription for Metoclopramide Oral Solution that is dispensed. The Medication Guide will also be available from www.wockhardtusa.com. Therefore, Morton Grove Pharmaceuticals (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 Metoclopramide Oral Solution is dispensed will be printed on the label of each bottle.

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

B. Communication Plan

This REMS for Metoclopramide Oral Solution does not include a Communication Plan.

C. Elements to Assure Safe Use

This REMS for Metoclopramide Oral Solution can be approved without Elements to Assure Safe Use.

D. Implementation System

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

E. Timetable for Submission of Assessments

The FDA has not requested that the Sponsor submit REMS Assessments for Metoclopramide Oral Solution.