

Metoclopramide Oral Solution USP, 5 mg/ 5 mL – ANDA # 71-402

**ANI Pharmaceuticals, Inc.
7131 Ambassador Road, Suite 150
Baltimore, MD 21244**

Risk Evaluation and Mitigation Strategy (REMS)

I. Goal

The goal of this REMS is to minimize the risks of tardive dyskinesia associated with long-term use of Metoclopramide Oral Solution.

II. REMS Elements

A. Medication Guide

A Medication Guide will be dispensed with each Metoclopramide Oral Solution prescription.

In accordance with 21 CFR 208.24, ANI will package a sufficient number of Medication Guides with each box containing 16 oz. of Metoclopramide Oral Solution USP, 5 mg/ 5 mL so that each patient receiving a prescription can receive a copy of the Medication Guide. ANI will package four copies of the Medication Guide in each 16 oz. dispensing bottle. This will permit the pharmacist to distribute a copy of the Medication Guide to each patient receiving a dispensed prescription. The dispensing bottle will inform the pharmacist to dispense the Medication Guide.

The Medication Guide is appended to the REMS.

B. Communications Plan

The REMS for metoclopramide oral solution does not include a Communication Plan.

C. Elements to Assure Safe Use

The REMS for metoclopramide oral solution does not include Elements to Assure Safe Use.

D. Implementation System

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

E. Timetable for Submission of Assessments

The REMS for ANDA 71-402, metoclopramide oral solution does not include a Timetable for Submission of Assessments.