NDA 22-246
METOZOLV™ ODT
(metoclopramide hydrochloride) Orally Disintegrating Tablets
5 mg & 10 mg

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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 for METOZOLV™ ODT (metoclopramide hydrochloride) Orally Disintegrating Tablets.

II. REMS ELEMENTS

A. Medication Guide

All professional samples given to patients by a health care professional shall include a Medication Guide enclosed in the carton to ensure that the safety information is distributed to the patient. The sample carton will prominently state: "Dispense the enclosed Medication Guide to each patient." Because there is only one blister sleeve per sample carton, the sleeve does not require a dispensing statement.

Each trade carton will contain four (4) medication guides with each box of 100 orally disintegrating tablets (10 blister sleeves). The number of Medication Guides is based upon research that indicates that the average number of tablets per prescription is currently 97 tablets. This will ensure that there is a sufficient number of medication guides provided with the product such that a dispenser can provide a medication guide with each prescription filled / refilled. In compliance with 21 CRF 208.24, the trade carton will prominently state: "Dispense the enclosed Medication Guide to each patient." Similarly, each blister sleeve in the trade carton will state: "Dispense the accompanying Medication Guide to each patient."

B. Communication Plan

This REMS for METOZOLV™ ODT (metoclopramide hydrochloride) Orally Disintegrating Tablets does not require a Communication Plan.

C. Elements to Assure Safe Use

This REMS for METOZOLV™ ODT (metoclopramide hydrochloride) Orally Disintegrating Tablets does not require Elements to Assure Safe Use.

D. Implementation System

This REMS for METOZOLV^{TM} ODT (metoclopramide hydrochloride) Orally Disintegrating Tablets does not require an Implementation System.

E. Timetable for Submission of Assessments

REMS Assessments will be submitted to FDA 18 months, 3 years, and 7 years after REMS approval (see table below). 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 date for that assessment. Salix will submit each assessment so that it will be received by the FDA on or before the due date.

Timetable for Submission of Assessments	
Assessment	Month/Year of Submission
1st Assessment (18 months from approval)	March 2011
2nd Assessment (3 years from approval)	September 2012
3rd Assessment (7 years from approval)	September 2016