

NDA 21-097 Visicol[®] (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets

NDA 21-892 OsmoPrep[®] (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1 GOAL(S)

The goal of the REMS for Visicol and OsmoPrep (sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrous) Tablets is to communicate the risks of acute phosphate nephropathy associated with the use of oral sodium phosphate products to healthcare professionals and patients.

2 REMS ELEMENTS

2.1 MEDICATION GUIDE

A Medication Guide will be dispensed with each Visicol and OsmoPrep prescription in accordance with 21 CFR 208.24. The appropriate number of Medication Guides along with the approved package insert will be provided directly to the pharmacy with each bottle of OsmoPrep and Visicol. Any multi-dose bottle will be shipped in a carton with multiple Medication Guides enclosed to allow dissemination to each patient. Product labels will prominently state that the Medication Guide should be dispensed to each patient.

All professional samples given to patients by a healthcare professional shall include a Medication Guide adhered to the primary packaging to ensure that the safety information is distributed to the patient.

The [Medication Guide](#) is appended.

2.2 COMMUNICATION PLAN

Salix will implement a communication plan to healthcare providers to support the implementation of the REMS. Salix will continue the communication plan until January 1, 2013.

2.2.1 Dear Healthcare Professional Letter

A Dear Healthcare Professional (DHCP) letter will be disseminated within 60 days of REMS approval and will include the revised prescribing information and Medication Guide. It will be distributed to healthcare professionals in family medicine, internal medicine, general surgery, gastroenterology, general practice, nephrology, colorectal surgery, and others who have prescribed or dispensed Visicol and/or OsmoPrep, performed follow-up assessments of patients following administration, or have been called on by Salix sales representatives within the past year.

The DHCP Letter, Medication Guide, and prescribing information will also be made available to approximately 70,000 national and regional pharmacies electronically and via e-mail to pharmacists and pharmacy technicians so that dispensers of the products are fully informed of the updated safety information and safe use of Visicol and OsmoPrep.

The [Dear Healthcare Professional Letter](#) is appended.

2.2.2 Educational Product Website

Salix will utilize the searchable online product website www.warninginfoforosmoprepandvisicol.com dedicated to inform and educate healthcare professionals on the safety, proper administration and use of Visicol and OsmoPrep Tablets.

The product website will include:

- Questions and answers regarding acute phosphate nephropathy, safety information and the safe use of OsmoPrep and Visicol
- A copy of the Dear Healthcare Professional Letter
- A copy of the Medication Guide for each product
- A copy of the current package insert for each product
- Suggested dosing regimen for each product
- Adverse event reporting contact

3 ELEMENTS TO ASSURE SAFE USE

This REMS for Visicol and OsmoPrep Tablets does not include elements to assure safe use.

4 IMPLEMENTATION SYSTEM

An implementation system is not required because this REMS for Visicol and OsmoPrep Tablets does not include elements to assure safe use.

5 TIMETABLE FOR SUBMISSION OF ASSESSMENTS

Salix will submit REMS Assessments to FDA 18 months, 3 years, and 7 years from the date of the 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 date for that assessment. Salix will submit each assessment-so that it will be received by the FDA on or before the due date.