

**NDA 022353**

**COLCRYS™ (colchicine, USP) tablets**

Mutual Pharmaceutical Company, Inc.  
Philadelphia, PA 19124

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**PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOAL(S)**

The goal of this REMS is to inform patients of the serious risks associated with the use of COLCRYS™ (colchicine), including the risks of increased susceptibility to colchicine toxicity in patients with renal or hepatic impairment and potential serious drug-drug interactions with colchicine.

**II. REMS ELEMENTS**

**A. Medication Guide**

A Medication Guide will be dispensed with each COLCRYS™ (colchicine, USP) tablets prescription in accordance with 21 CFR 208.24.

In accordance with 21 CFR 208.24(b), Mutual will ensure that the Medication Guide is available for distribution to patients by providing the Medication Guide in sufficient numbers to distributors, packers or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription of COLCRYS™ (colchicine, USP) tablets.

Sufficient numbers of Medication Guides will be included with each COLCRYS™ (colchicine, USP) tablets bottle along with the Prescribing information. Sufficient numbers of Medication Guides will be attached to or provided with each bottle such that one Medication Guide is dispensed with each 30 day supply. Packaging the product literature with the bottles ensures that every patient receives the Medication Guide with each COLCRYS™ (colchicine, USP) tablets prescription.

Mutual will also make the Medication Guide available through use of tear pads or on our website, [www.COLCRYS.com](http://www.COLCRYS.com).

In accordance with 21CFR 208.24 (d), Mutual will include a statement on the container labels for COLCRYS™ (colchicine, USP) tablets to alert pharmacists to dispense the Medication Guide with the product.

**B. Timetable for Submission of Assessments**

	<b>Month/Year of Submission</b>
<b>1st REMS Assessment (18 months from approval date)</b>	April 2011
<b>2<sup>nd</sup> REMS Assessment (3 years from approval date)</b>	October 2012
<b>3<sup>rd</sup> REMS Assessment (7 years from approval date)</b>	October 2016

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. Mutual will submit each assessment so that it will be received by the FDA on or before the due date.