CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-351

REMS

NDA 22-351

COLCRYS™ (colchicine, USP) tablets

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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

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. Communication Plan

This REMS for COLCRYS™ (colchicine, USP) tablets does not include a communication plan.

C. Elements To Assure Safe Use

This REMS for COLCRYS™ (colchicine, USP) tablets does not include elements to assure safe use.

D. Implementation System

Because this REMS for COLCRYS™ (colchicine, USP) tablets does not include elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

The Timetable for Assessments is as follows:

1st Assessment: 18 months post approval
2nd Assessment: 3 years post approval
3rd Assessment: 7 years post approval.

Mutual will submit the assessments within 60 days of the close of the interval as noted above.