

Colchicine no longer marketed

FDA notified healthcare professionals of the approval of the first single-ingredient oral colchicine product, Colcrys, for the treatment of familial Mediterranean fever (FMF) and acute gout flares and of two previously uncharacterized safety concerns associated with the use of colchicine. Oral colchicine has been used for many years as an unapproved drug with no FDA-approved prescribing information, dosage recommendations, or drug interaction warnings.

FDA analyzed safety data for colchicine from adverse events reported to the Agency, the published literature, and company-sponsored pharmacokinetic and drug interaction studies. This analysis revealed cases of fatal colchicine toxicity reported in certain patients taking standard therapeutic doses of colchicine and concomitant medications that interact with colchicine, such as clarithromycin. These reports suggest that drug interactions affecting the gastrointestinal absorption and/or hepatic metabolism of colchicine play a central role in the development of colchicine toxicity. Data submitted supporting the safety and efficacy of Colcrys in acute gout flares demonstrated that a substantially lower dose of colchicine was as effective as the higher dose traditionally used. Moreover, patients receiving the lower dose experienced significantly fewer adverse events compared to the higher dose.

Based on this information, FDA has included important safety considerations in the approved prescribing information to assure safe use of Colcrys and is providing background information, a data summary and recommendations in this alert.