LSU HEALTH SCIENCES CENTER – SHREVEPORT
PHARMACY & THERAPEUTICS COMMITTEE

SUBJECT:	**Colchicine**	**REFERENCE #: 2.3**	
APPROVED BY:	**P&T Committee**	**WRITTEN: 2/11**	**Page 1 of 2**

Purpose: To identify Colchicine IV as a high alert medication and provide guidelines for the safe administration of this medications to patients.

Prescribing: Can only be prescribed by Rheumatology physicians

FDA: On 5/15/2009, the FDA updated the enforcement action against IV Colchicine. In addition to being manufactured by pharmaceutical companies, injectable colchicine products are sometimes formulated by compounding pharmacies. There are serious risks associated with the compounding of injectable colchicine products because there is a limited margin of safety due to the narrow therapeutic index and serious toxicities associated with colchicine. Any concentration errors that occur within the course of compounding injectable colchicine can have potentially serious and fatal consequences. FDA is aware of a number of deaths attributed to improperly compounded injectable colchicine products and discourages the compounding of these products due to the serious safety risks.

On 2/8/2008, the FDA has ordered individuals and companies to stop making intravenous colchicine products within 30 days and to stop shipping the product within 180 days. After these dates, all injectable colchicine drug products must have FDA approval in order to be manufactured or shipped interstate.

Drug products containing colchicine for intravenous use have been marketed without approval. Colchicine is a drug which, when not properly dosed, can produce harmful or fatal effects including abdominal pain, vomiting, seizures, lack of blood cell production, and organ failure. Because injectable colchicine is a toxic drug, and also a drug with a narrow margin between an effective dose and a toxic dose, proper manufacturing and dosing recommendations are essential. These can only be assured by making certain that the products are held to the rigorous safety and efficacy standards of the FDA approval process. This action affects all injectable colchicine products, as none currently have FDA approval. There was one manufacturer of injectable colchicine, but that firm voluntarily discontinued manufacture of injectable colchicine in October 2007.

References:

1. *www.fda.gov › ... › Enforcement Activities by FDA*
2. Micromedex.