

## **FDA Incentives for Drug Companies Make Colchicine Inaccessible to FMF Patients in the US**

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Colchicine, an ancient, globally available, low cost drug is the gold standard treatment for familial Mediterranean fever (FMF), since 1972. Access to colchicine is critical for the optimal treatment of FMF. FDA drug approval policies that permit exploitive market manipulation, have severely reduced colchicine access. In **2009** the FDA granted a three year proprietary period for Colcrys brand colchicine for treatment of gout, under the FDA's **Unapproved Drug Initiative**, plus a seven year proprietary period under the **Orphan Drug Act** for treatment of FMF. The FDA waived the requirement for a clinical trial in FMF patients under the **505(b)(2) application** which allows submission of trial data from a different brand of colchicine. All other brands of colchicine were banned. An immediate **50-fold increase in price** was imposed from \$0.09 to \$4.85 per 0.6mg tablet. Insurers bore most of the price increase. Colcrys was found to have an **81% adverse response rate\*** forcing FMF patients to seek foreign sources of colchicine, paying out of pocket. In **2015**, a second brand of colchicine, Mitigare, was approved, but was marketed at the **same price as Colcrys**, perpetuating the hyperinflated price. In **2017** the FDA's regulatory largess came full circle when the largest healthcare insurers in the US **dropped insurance coverage** for colchicine due to its hyperinflated price, requiring FMF patients to pay out of pocket for domestic brands. As of January 2017 the following sources of colchicine were legally available to FMF patients in the US, shown with the **out of pocket cost** for each one. Prices are for 1 year, 2.0mg per day.

**\$6,789** Mitigare ( CVS pharmacy, US)

**\$7,380** Colcrys (CVS pharmacy, US)

**\$424** Canadian online pharmacy (lowest cost brand, Kolsin)

**\$88** Mexican brand Sixol (purchased in Mexico)

**\$367** Mexican brand Sixol (including round trip, same day airfare, NY - Cancun)

\*J Jagger, J McGonagle. Colchicine brand switching in FMF patients: A Therapeutic Strategy. Pediatric Rheumatology 2013, 11(Suppl 1):A60.

<https://www.mitigare.com/physicians/colchicine-history/>

<https://www.mitigare.com/physicians/colchicine-history/505-b2/>

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