

Initial Quantity Limit Colchicine

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Colcrys	colchicine
Gloperba	colchicine solution
Mitigare	colchicine

Indications

FDA-Approved Indications

Colcrys

Gout Flares

Colcrys (colchicine, USP) tablets are indicated for prophylaxis and the treatment of acute gout flares.

- Prophylaxis of Gout Flares: Colcrys is indicated for prophylaxis of gout flares.
- Treatment of Gout Flares: Colcrys tablets are indicated for treatment of acute gout flares when taken at the first sign of a flare.

Familial Mediterranean Fever (FMF)

Colcrys (colchicine, USP) tablets are indicated in adults and children four years or older for treatment of familial Mediterranean fever (FMF).

Reference number(s)
678-H

Compendial Uses

Behcet's Syndrome ^{6,8}

Pericarditis, Recurrent; Prophylaxis ^{6,7}

Gloperba

Gloperba (colchicine USP) Oral Solution is indicated for prophylaxis of gout flares in adults.

Limitations of use

The safety and effectiveness of Gloperba for acute treatment of gout flares during prophylaxis has not been studied. Gloperba is not an analgesic medication and should not be used to treat pain from other causes.

Mitigare

Mitigare (colchicine) capsules are indicated for prophylaxis of gout flares in adults.

Limitations of use

The safety and effectiveness of Mitigare for acute treatment of gout flares during prophylaxis has not been studied. Mitigare is not an analgesic medication and should not be used to treat pain from other causes.

Initial Limit Quantity

Limits should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Colcrys	120 tablets / 25 days	360 tablets / 75 days
Mitigare	60 capsules / 25 days	180 capsules / 75 days
Gloperba	300 mL / 25 days	900 mL / 75 days

References

1. Colcrys [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2020.
2. Gloperba [package insert]. Palto Alto, CA: Scilex Pharmaceuticals, LLC; August 2022.
3. Mitigare [package insert]. Memphis, TN: Hikma Specialty USA Inc.; May 2024.

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4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 23, 2024.
5. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 23, 2024.
6. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/23/2024).
7. Imazio M, Brucato A, Cemin R, et al. Colchicine for Recurrent Pericarditis (CORP): a randomized trial. *Ann Intern Med*. 2011;155(7):409-414.
8. NORD. Behçet's Syndrome. Last updated 05/17/2023. Available at: <https://rarediseases.org/rare-diseases/behcets-syndrome/#therapies> Accessed October 23, 2024.
9. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. *Arthritis Rheumatol*. 2020;72(6):879-895.