

## Lodoco® (colchicine) - New drug approval

- On June 20, 2023, <u>Agepha Pharma announced</u> the FDA approval of <u>Lodoco (colchicine)</u>, to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular (CV) death in adult patients with established atherosclerotic disease or with multiple risk factors for CV disease.
- Lodoco is the first colchicine formulation approved for CV disease.
  - Other colchicine formulations are available generically and approved for gout and familial Mediterranean fever.
- The efficacy of colchicine in patients with CV events is derived from published literature (LoDoCo2) along with other supportive studies. LoDoCo2 was an investigator-initiated, randomized, placebo controlled, double-blind, event-driven study in 5,522 patients with stable coronary artery disease. Patients received Lodoco or placebo. The primary endpoint was a composite of CV death, spontaneous (nonprocedural) MI, ischemic stroke, or ischemia-driven coronary revascularization.
  - Treatment with colchicine resulted in a 31% lower relative risk of the primary composite endpoint events compared to placebo (hazard ratio 0.69, 95% CI: 0.57, 0.83; p < 0.001) and the number needed to treat was 36.
- Lodoco is contraindicated in patients with:
  - Concurrent use of strong CYP3A4 inhibitors or P-glycoprotein inhibitors
  - Renal failure and severe hepatic impairment
  - Pre-existing blood dyscrasias and in patients hypersensitive to this drug or any inactive ingredient of Lodoco.
- Warnings and precautions for Lodoco include blood dyscrasias and neuromuscular toxicity.
- The common side effects reported in published clinical studies and literature with the use of colchicine are gastrointestinal symptoms (diarrhea; vomiting; abdominal cramping) and myalgia.
- The recommended dose of Lodoco is 0.5 mg orally once daily.
- Agepha Pharma plans to launch Lodoco in the second half of 2023. Lodoco will be available as a 0.5 mg tablet.



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