



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 May 2026
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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Colchicine Agepha Pharma

colchicine

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the granting of a marketing authorisation for the medicinal product Colchicine Agepha Pharma, intended for the secondary prevention of atherothrombotic events in adults with coronary disease who have been stable for at least 6 months.

The applicant for this medicinal product is Agepha Pharma s.r.o.

Colchicine Agepha Pharma will be available as 0.5 mg tablets. The active substance of Colchicine Agepha Pharma is colchicine, an antigout preparation with no effect on uric acid metabolism (ATC code: M04AC01). Colchicine is an anti-inflammatory medicinal product that inhibits the migration of granulocytes to the inflamed areas, inhibit microtubule polymerisation and modulates inflammatory pathways implicated in atherosclerosis.

Colchicine Agepha Pharma is a hybrid medicine² of Colchicine Tiofarma 0.5 mg tablets, which has been authorised in the EU since 1998. Colchicine Agepha Pharma contains the same active substance as Colchicine Tiofarma but differs in the approved indication.

Studies have demonstrated the satisfactory quality of Colchicine Agepha Pharma, and its bioequivalence to the reference product Colchicine Tiofarma.

The benefits of Colchicine Agepha Pharma are its ability to significantly reduce the time to first occurrence of cardiovascular death, spontaneous myocardial infarction, ischaemic stroke, or ischaemia-driven coronary revascularisation compared with placebo in randomised study in patients with stable coronary artery disease for at least 6 months. The most common side effects with Colchicine Agepha Pharma include gastrointestinal disorders such as diarrhoea, nausea, vomiting, abdominal pain and cramping.

The full indication is:

Colchicine AGEPHA Pharma is indicated for secondary prevention of atherothrombotic events in

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

² Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data.



adult patients with coronary disease stable for at least 6 months.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.