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Colchicine Agepha Pharma (*colchicine*)

A plain-language overview of Colchicine Agepha Pharma and why it is authorised in the EU

What is Colchicine Agepha Pharma and what is it used for?

Colchicine Agepha Pharma is a medicine used in adults, in addition to standard therapy, to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries), such as heart attacks or strokes. It is used in people with coronary disease that has been stable for more than 6 months. Coronary disease is a heart disease caused by narrowing or blockage of blood vessels supplying the heart muscle.

Colchicine Agepha Pharma contains the active substance colchicine and is a hybrid medicine. This means that it is similar to a reference medicine containing the same active substance, but the medicines are authorised for different conditions. The reference medicine, Colchicine Tiofarma, is authorised in some EU Member States for the treatment and prevention of various inflammatory conditions (such as acute gout).

How is Colchicine Agepha Pharma used?

Colchicine Agepha Pharma can only be obtained with a prescription. It is available as tablets to be taken by mouth once a day. It can be used safely for 28 months. The recommended maximum dose of colchicine should not be exceeded. The doctor may decide to reduce the dose or stop treatment if the patient has diarrhoea, nausea or vomiting, as these may be signs of side effects caused by too much medicine in the body.

For more information about using Colchicine Agepha Pharma, see the package leaflet or contact your doctor or pharmacist.

How does Colchicine Agepha Pharma work?

Colchicine is a well-known substance that has been used for decades for the treatment of various inflammatory disorders.

The way colchicine works in the prevention of atherothrombotic events is not fully understood. However, it is thought to reduce inflammation by disrupting the structure of certain white blood cells

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involved in inflammation. This prevents these cells from moving to areas of inflammation and releasing inflammatory substances. This is thought to prevent damage to the heart and blood vessels.

What benefits of Colchicine Agepha Pharma have been shown in studies?

Studies from the medical literature have shown that medicines containing low-dose colchicine reduce the risk of cardiovascular events in patients with stable coronary artery disease when added to standard therapy.

A study from the literature included 5,522 patients with chronic (long-term) coronary artery disease that had been stable for at least 6 months. Most people had previously had cardiovascular problems such as a heart attack, and were already being treated with standard therapy, including lipid-lowering medicines and antiplatelet therapy. They received either low-dose colchicine or placebo (a dummy treatment), in addition to their standard therapy, and were followed for a median of almost 29 months (median means that half the patients were followed for 29 months or more and half for less than 29 months).

The study looked at whether patients had one of the following events during the study: cardiovascular death (death due to a heart or blood vessel problem), spontaneous myocardial infarction (a heart attack not linked to a surgical procedure), ischaemic stroke (a stroke caused by a blockage in a blood vessel) or ischaemia-driven coronary revascularisation (a procedure like a stent or bypass to improve blood flow to the heart). One of these events occurred in 6.8% of patients who had colchicine (187 out of 2,762) and 9.6% of patients who had placebo (264 out of 2,760).

Eight additional studies from the medical literature provided further evidence of the benefits of using colchicine medicines in addition to standard therapy to prevent atherothrombotic events in people with stable coronary disease.

In addition, Colchicine Agepha Pharma has been shown to have the same effects in the body as the reference medicine Colchicine Tiofarma, which was used in most of these studies.

Studies that supported the authorisation of Colchicine Agepha Pharma are described in more detail in the medicine’s assessment report.

What are the side effects and restrictions with Colchicine Agepha Pharma?

For the full list of side effects and restrictions with Colchicine Agepha Pharma, see the package leaflet.

The most common side effects with Colchicine Agepha Pharma (which may affect more than 1 in 10 people) include gastrointestinal (stomach and gut) problems such as diarrhoea, nausea (feeling sick), vomiting, and abdominal (stomach) pain or cramping.

Diarrhoea, which can be accompanied with nausea and vomiting, may be the first sign of an overdose, which can lead to serious, painful and irreversible effects.

In the medical literature, colchicine has been reported to affect the nerves and muscles (neuromuscular effects), which may present as muscle pain or weakness. Serious side effects include myelosuppression (a condition in which the bone marrow cannot make enough blood cells), disseminated intravascular coagulation (a condition causing small blood clots to form throughout the body), and problems with the kidneys, liver, blood circulation and nervous system.

Colchicine Agepha Pharma must not be used with medicines known as CYP3A4 inhibitors or P-glycoprotein inhibitors. People with blood dyscrasia (problems affecting the blood, bone marrow or lymph tissue), kidney problems or severe liver problems must not use Colchicine Agepha Pharma.

Why is Colchicine Agepha Pharma authorised in the EU?

Colchicine has been shown in the medical literature to reduce the risk of atherothrombotic events in people with stable coronary disease when used together with standard therapies. In terms of safety, although the data available in people with coronary disease are limited, the safety profile of colchicine when used in other conditions is well understood, and no new safety concerns have been identified when colchicine is used in people with coronary disease. The known gastrointestinal and neuromuscular effects of colchicine are adequately addressed in the product information for Colchicine Agepha Pharma.

Colchicine Agepha Pharma has been shown to be similar to an authorised medicine containing colchicine. The European Medicines Agency therefore decided that Colchicine Agepha Pharma's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Colchicine Agepha Pharma?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Colchicine Agepha Pharma have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Colchicine Agepha Pharma are continuously monitored. Suspected side effects reported with Colchicine Agepha Pharma are carefully evaluated and any necessary action is taken to protect patients.

Other information about Colchicine Agepha Pharma

Colchicine Agepha Pharma received a marketing authorisation valid throughout the EU on 24 July 2026.

Further information on Colchicine Agepha Pharma, including the package leaflet and assessment report(s), can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Colchicine-Agepha-Pharma.

For information about the availability of this medicine in your country, contact your national competent authority.