

Summary Public Assessment Report

non-generics

**Colchicine IASIS 0.25 mg/ml oral solution
(colchicine)**

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Colchicine IASIS

Colchicine, oral solution, 0.25 mg/ml

This is a summary of the public assessment report (PAR) for Colchicine IASIS. It explains how Colchicine IASIS was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Colchicine IASIS.

For practical information about using Colchicine IASIS, patients should read the package leaflet or contact their doctor or pharmacist.

What is Colchicine IASIS and what is it used for?

Colchicine IASIS is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as 0.25 mg/ml oral solution. Differences from reference product are:

- change in strength (quantitative change to the active substance)
- change in pharmaceutical form
- change in therapeutic indications

The company has provided additional own data to demonstrate the safety and efficacy of Colchicine IASIS regarding these differences from the reference medicine.

The reference medicine for Colchicine IASIS is Colchicine Tiofarma 0.5 mg tabletten.

Colchicine IASIS is used in adults:

- for the treatment of acute gout, so called gout attacks
- for the prophylaxis of a gout attack during initiation of urate-lowering therapy
- for the treatment of acute and recurrent pericarditis (a heart membrane inflammation) as an adjunct to aspirin/NSAID therapy.

In adults, children and adolescents up to 18 years of age, Colchicine IASIS is indicated in Familial Mediterranean Fever (FMF) for prophylaxis of attacks and prevention of amyloidosis, a rare disease that occurs when a protein called amyloid builds up in organs.

How does Colchicine IASIS work?

Colchicine IASIS contains the active substance colchicine. It belongs to the group of anti-gout agents and is used to prevent or treat a gout attack.

The concentration of uric acid in blood is increased in gout. This might lead to precipitation of uric acid crystals in the fluid of joints. Colchicine inhibits the resulting inflammatory response.

How is Colchicine IASIS used?

The pharmaceutical form of Colchicine IASIS is oral solution and the route of administration is oral use (taken by mouth).

Use in adults

Use in gout

Treatment of acute gout attack:

The recommended dose is 2 ml oral solution (0.5 mg colchicine) two to three times daily. Your doctor may decide to prescribe an additional 4 ml oral solution (1 mg colchicine) for the first day of treatment. Treatment should end until the acute attack resolves, or earlier in the event of gastrointestinal symptoms or no effect after 2 to 3 days.

You should not take more than 24 ml oral solution (6 mg colchicine) during a course of treatment.

After completion of a course of Colchicine IASIS (or other medicine containing colchicine), you should not start another course for at least three days (72 hours).

Prophylaxis of a gout attack:

The recommended dose is 2 – 4 ml oral solution (0.5 – 1 mg colchicine) per day and should be taken in the evening. Your doctor will tell you how long your treatment with Colchicine IASIS will last.

Dosing in impaired liver or kidney function

If you have impaired liver or kidney function the recommended dose is 2 ml oral solution (0.5 mg colchicine) per day and you should be carefully monitored. If you have severely impaired hepatic or kidney function you should not use this medicine, see section 2 of the PL “Do not take Colchicine IASIS”.

Use in acute and recurrent pericarditis

The recommended dose is 2 ml oral solution (0.5 mg colchicine) per day if your body weight is less than 70 kg or if you do not tolerate higher doses.

The recommended dose is 2 ml oral solution (0.5 mg colchicine) twice daily if your body weight is more than 70 kg.

Continue the treatment for 3 months in acute pericarditis and 6 months in recurrent pericarditis.

However, the dose will be determined by your doctor, based on your clinical picture (kidneys and liver function).

Children and adolescents

Colchicine IASIS should not be used for the treatment of acute gout, prophylaxis of a gout attack and in acute and recurrent pericarditis in children and adolescents.

Use in Familial Mediterranean Fever

Use in adults

The recommended dose is 4 – 12 ml oral solution (1 – 3 mg colchicine) per day. The daily dose may be taken as a single dose or may be divided over two doses daily (for doses over 4 ml oral solution per day).

If you do not respond to the standard dosage, your doctor may increase the dose of colchicine in a stepwise fashion up to a maximum of 12 ml oral solution (3 mg colchicine) per day. You should be carefully monitored by your doctor for side effects with any increase in the dose of colchicine.

Use in children and adolescents up to 18 years of age

Colchicine is potentially toxic so it is important not to exceed the dose prescribed by your doctor.

In children and adolescents with Familial Mediterranean Fever the recommended posology is based on age.

The following daily doses may be given as a single dose or divided dose twice daily (for doses over 4 ml oral solution per day):

- Children <5 years of age: 2 ml oral solution (0.5 mg colchicine) per day
- Children from 5 to 10 years of age: 4 ml oral solution (1 mg colchicine) per day

- Children >10 years of age: 6 ml oral solution (1.5 mg colchicine) per day

Children and adolescents with amyloid nephropathy

Colchicine dosage should be increased in a stepwise fashion (0.25 mg/step) up to a maximum of 8 ml oral solution (2 mg colchicine) per day. Any increase of the daily dose should be monitored closely for side effects.

Dosing in impaired liver or kidney function

If you have impaired liver or kidney function the recommended dose will be halved. If you have severely impaired hepatic or kidney function you should not use this medicine, see section 2 of the PL “Do not take Colchicine IASIS”.

Route/method of administration

Colchicine IASIS is for oral use only.

The syringe should be used to measure your dose by drawing the liquid to the correct mark on the syringe.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Colchicine IASIS have been shown in studies?

Because Colchicine IASIS is a hybrid application of Colchicine Tiofarma, clinical studies have been provided for Colchicine IASIS to show efficacy for the difference of Colchicine IASIS from the reference product Colchicine Tiofarma.

What are the possible side effects from Colchicine IASIS?

The common side effects with Colchicine IASIS (which may affect up to 1 in 10 people) are nausea, vomiting, abdominal pain and diarrhea.

For the full list of all side effects reported with Colchicine IASIS, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Colchicine IASIS approved?

The State Institute for Drug Control decided that Colchicine IASIS's benefits are greater than its risks and recommended that it can be approved for use.

Other information about Colchicine IASIS

The marketing authorisation for Colchicine IASIS was granted on 12 September 2025.

The full PAR for Colchicine IASIS can be found on the [website](#). For more information about treatment with Colchicine IASIS, read the package leaflet ([PL](#)) or contact your doctor or pharmacist.

This summary was last updated in 01-2026.