

Colchicine 250 micrograms/ml oral solution

colchicine

Important warning!

Do not exceed the recommended dose. Overdosing, including by ignoring interactions, can lead to a very painful and irreversible poisoning with a fatal outcome. Please refer to Sections 2, 3 and 4 of this package leaflet. The medicinal product must be kept out of reach of others before and after use.

The name of your medicine is Colchicine 250 micrograms/ml oral solution which will be referred to as ‘Colchicine oral solution’ throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What Colchicine oral solution is and what it is used for
- What you need to know before you use Colchicine oral solution
- How to use Colchicine oral solution
- Possible side effects
- How to store Colchicine oral solution
- Contents of the pack and other information

1 What Colchicine oral solution is and what it is used for

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

Gout attacks in adults

This medicine is used in adults in the short-term treatment of acute gout, so called gout attacks and for the prevention of a gout attack during initiation of urate-lowering therapy.

The concentration of uric acid in the blood is increased in gout, which can cause uric acid crystals to form in the fluid of joints. Colchicine helps by reducing the resulting inflammatory response.

Familial Mediterranean Fever

In addition, this medicine is indicated in Familial Mediterranean Fever to prevent fever attacks and amyloidosis (abnormal precipitation of proteins in tissues and organs).

Acute and Recurrent Pericarditis

This medicine is used in adults to treat acute and recurrent Pericarditis (heart membrane inflammation), alongside aspirin/NSAID therapy.

You must talk to a doctor if you do not feel better or if you feel worse.

2 What you need to know before you use Colchicine oral solution

Do not use Colchicine oral solution:

- If you are allergic to colchicine or any of the other ingredients of this medicine (listed in section 6).
- If you have a severe blood disorder.
- If you have severe kidney problems.
- If you have severe liver problems.

Warnings and precautions

There is a slight difference between an effective dose of this medicine and a dose that causes symptoms of medicine overdose, this means that even a little too high a dose can cause acute signs of a medicine overdose. If you get symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking this medicine and immediately contact your doctor (see also section 4 ‘Possible side effects’).

Talk to your doctor, pharmacist or nurse before using this medicine if one or more of the following situations apply to you or have been applicable in the past.

- If you have problems with your liver or kidneys.
- If you have heart or vascular disease.
- If you have problems with your gastrointestinal tract.
- If you are elderly and weak.
- If you have a blood disorder.
- If you are pregnant or lactating.

Colchicine can cause a severe decrease in bone marrow function (disappearance of certain white blood cells (agranulocytosis), shortage of blood platelets (thrombocytopenia), decrease in red blood cells and pigment due to a lack of production of red blood cells (aplastic anaemia)).

You should have regular blood tests to monitor any changes.

If you have pre-existing blood dyscrasias, gastrointestinal disease, elevated aminotransferase, creatinine or troponin levels, severe liver disease, myopathy and bacterial or neoplastic pericarditis you should avoid this medicine and talk to your doctor.

If you develop symptoms such as fever, inflammation of the mouth, sore throat, prolonged bleeding, bruising or skin problems, stop taking this medicine and contact your doctor immediately. These could be signs that you have a serious blood problem, and your doctor may want you to have blood tests straight away (see also section 4 ‘Possible side effects’).

Long-term use of colchicine may lead to a vitamin B12 deficiency.

Children and adolescents to 18 years

For use in children, colchicine should only be prescribed under the supervision of a medical specialist only in Familial Mediterranean Fever for prophylaxis of attacks and prevention of amyloidosis. No data is available regarding the effect of long-term colchicine use in children.

For the indications treatment of acute gout, prevention of a gout attack and treatment of acute and recurrent pericarditis, safety and effectiveness in children have not been established.

Other medicines and Colchicine oral solution

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Caution is advised when this product is used together with medicines that may impair your blood count or negatively influence your liver and kidney function. In this case, contact your doctor.

If this medicine is taken together with any of the following medicines, side effects due to colchicine toxicity are more likely and these can be very serious. You must talk to your doctor, pharmacist or nurse if you are taking:

- erythromycin, telithromycin, clarithromycin and azithromycin (certain antibiotics, medicines used to treat bacterial infections). The use of these kind of antibiotics during the period you are being treated with colchicine may cause medicine overdose. If possible, do not use these kinds of antibiotics during the period that you are being treated with colchicine. When no other treatment is possible, your doctor may lower the dose of colchicine and keep you under surveillance.
- ketoconazole, itraconazole, voriconazole (anti-fungal medicines). You should not use these medicines during the period you are being treated with colchicine.
- ritonavir, atazanavir, amprenavir, saquinavir, nelfinavir, fosamprenavir and indinavir (certain protease inhibitors used to treat HIV infection). You should not use these medicines during the period you are being treated with colchicine.
- verapamil, quinidine and diltiazem (medicines used to treat heart disease).
- ciclosporin (medicine used to reduce the body’s resistance to infection by suppressing the immune system).

For patients with an impaired renal or hepatic function or of any degree, the combined use of colchicine and P-gp inhibitors and/or strong CYP3A4 inhibitors should be avoided whenever possible.

Also tell your doctor, pharmacist or nurse if you are taking any of the following:

- Taking the following medicines during the period you are being treated with colchicine may cause a serious muscle disease (myopathy) and breakdown of muscle tissue, which is accompanied by muscle cramps, fever and red-brown discolouration of urine (rhabdomyolysis):
 - simvastatin, fluvastatin or pravastatin (statins, medicines used to lower cholesterol).
 - fibrates (medicines used to lower cholesterol and some fats in the blood).
 - digoxin (medicine used to treat heart failure and arrhythmias).
- cimetidine (used to reduce intestinal or gastric ulcers) and tolbutamide (used to lower blood sugar). They can increase the effect of colchicine.
- vitamin B12 (cyanocobalamin). Absorption of vitamin B12 from the gastrointestinal tract may be reduced by colchicine.

This medicine with food and drink

You should not drink grapefruit juice during the period you are being treated with colchicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

Women of childbearing potential:

Treatment of gout

Women of childbearing potential have to use effective contraception during and for at least 3 months following termination of Colchicine oral solution treatment for gout. If, nevertheless, pregnancy occurs during this time period, genetic counselling should be undertaken.

Pregnancy:

Treatment of gout:

You should not use this medicine if you are or may become pregnant. If, nevertheless, pregnancy occurs during the treatment with this medicine or within 3 months after termination of treatment, genetic counselling should be undertaken.

Treatment of FMF:

Since the course of FMF without treatment may also negatively influence pregnancy, the use of this medicine during pregnancy should be weighed against the potential risks and may be considered, if clinically needed.

Breast-feeding:

The active substance colchicine passes into your breast milk.

This medicine should not be used in breast-feeding women with gout.

In lactating mothers with FMF, a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from colchicine therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility:

Treatment of gout:

Male patients should not father a child during and for at least 6 months following termination of colchicine therapy. If, nevertheless, pregnancy occurs during this time period, genetic counselling should be undertaken.

Treatment of FMF:

Since the course of FMF without treatment may also lead to infertility, the use of this medicine should be weighed against the potential risks and may be considered, if clinically needed.

Driving and using machines

No data is available regarding the influence of colchicine on the ability to drive and use machines. However, the possibility of drowsiness and dizziness should be taken into account.

This medicine contains Sodium methyl parahydroxybenzoate (E219)

May cause allergic reactions (possibly delayed).

This medicine contains sodium

This medicine contains less than 1 mmol sodium (23mg) per ml, that is to say essentially ‘sodium-free’.

3 How to use Colchicine oral solution

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, nurse or a pharmacist if you are not sure.

In too high a dose colchicine is potentially toxic, so it is important not to exceed the dose prescribed by your doctor.

Contact your doctor, pharmacist or nurse if you feel that the effect of colchicine oral solution is too strong or not strong enough.

Use in adults

Use in gout

Treatment of an acute gout attack:

The recommended dose is 500 micrograms (2ml) daily two to four (2-4) times per day until symptoms are relieved or when a total of 24ml Colchicine has been taken. You should not take more than 24ml Colchicine as a course of treatment. Treatment should end in the event of gastrointestinal symptoms or no effect after 2 to 3 days.

You should not take more than 6000 micrograms (24ml) of this medicine during a course of treatment.

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

Prevention of gout attack:

The recommended dose is 500-1000 micrograms/day (2-4ml/day) and should be taken in the evening. Your doctor will tell you how long your treatment with this medicine will last.

Use in Acute and Recurrent Pericarditis

The recommended dose is 500 micrograms/day (2ml/day) for patients weighing ≤70kg or if you do not tolerate higher doses.

The recommended dose is 500 micrograms (2ml) twice daily for patients with a body weight of >70kg. However, the dose will be determined by your doctor, based on your clinical picture (kidneys and liver function).

Treatment duration is 6 months in recurrent pericarditis and 3 months in acute pericarditis.

If you have kidney or liver problems

If you have impaired liver or kidney function the recommended dose is 500 micrograms/day (2ml/day) and you should be carefully monitored. If you have severely impaired hepatic or renal function you should not use this medicine, see section 2 above ‘Do not take Colchicine oral solution’.

Children and adolescents

This medicine should not be used to treat acute gout, prevention 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 1000-3000 micrograms/day (4-12ml/day). The daily dose may be taken as a single dose or may be divided over two doses daily (for doses over 1000 micrograms/day).

If you do not feel better, your doctor may increase the dose of colchicine in a stepwise fashion up to a maximum of 3000 micrograms/day (12ml/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 with Familial Mediterranean Fever the recommended dosage is based on age. The following daily doses may be given as a single dose or divided dose twice daily (for doses over 1000 micrograms/day (4ml/day):

- Children <5 years of age: 500 micrograms/day (2ml/day)
- Children 5 to 10 years of age: 1000 micrograms/day (4ml/day)
- Children >10 years of age: 1500 micrograms/day (6ml/day)

Children and adolescents with amyloid nephropathy

Colchicine dosage should be increased in a stepwise fashion (250 micrograms/step) up to a maximum of 2000 micrograms/day (8ml/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 liver or kidney function you should not use this medicine, see section 2 above ‘Do not take Colchicine oral solution’.

Mode of administration

To remove the cap, push it down and turn it anti-clockwise. There is a 5ml oral syringe (graduated in 0.1ml steps), which should be used to take the medicine.

Table 1 – Colchicine dosage instructions				
Indication	Patient Group	Dose (µg)	Frequency	Special Notes
Acute Gout Attack	Adults	500 micrograms (2ml)	2–4 times daily	Maximum dose: 6,000 micrograms (24ml) per course. Stop when symptoms resolve or max dose reached. Wait ≥72 hrs before the next course. Discontinue if diarrhoea or vomiting occurs.
	Renal impairment	500 micrograms (2ml)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Hepatic impairment	500 micrograms (2ml)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Children	Not suitable for paediatric use.		
Prophylaxis of gout attack	Adults	500–1,000 micrograms (2–4ml)	Once daily (evening)	
	Renal impairment	500 micrograms (2ml)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Hepatic impairment	500 micrograms (2ml)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Children	Not suitable for paediatric use.		
Acute Pericarditis	Adults ≤70 kg or intolerant to high doses	500 micrograms (2ml)	Once daily	Duration: 3 months
	Adults >70 kg	500 micrograms (2ml)	Twice daily	Duration: 3 months
	Renal impairment	500 micrograms (2ml)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Hepatic impairment	500 micrograms (2ml)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Children	Not suitable for paediatric use		
Recurrent Pericarditis	Adults ≤70 kg or intolerant to high doses	500 micrograms (2ml)	Once daily	Duration: 6 months
	Adults >70 kg	500 micrograms (2ml)	Twice daily	Duration: 6 months
	Renal impairment	500 micrograms (2ml)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Hepatic impairment	500 micrograms (2ml)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Children	Not suitable for paediatric use		

Indication	Patient Group	Dose (µg)	Frequency	Special Notes
Familial Mediterranean Fever (FMF)	Adults	1,000–3,000 micrograms (4-12ml)	Once daily or doses higher than 1,000 micrograms can be divided twice daily	Maximum dose: 3,000 micrograms/day (12ml/day). Increase dose in stepwise fashion (e.g. 250 micrograms steps). Monitor for adverse effects.
	Renal impairment	Reduce FMF starting dose by 50% (e.g. ≤ 1000 micrograms /day)	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Hepatic impairment	Reduce FMF starting dose by 50% (e.g. ≤ 1000 micrograms /day).	Once daily	Do not use this medicine if you take any CYP3A4/P-gp inhibitors.
	Children <5 yrs	Starting dose: 500 micrograms (2ml)	Once daily	Specialist supervision required. Maximum dose: Up to 2000 micrograms (8ml). In children with amyloid nephropathy, higher daily doses up to 2,000 micrograms/day (8ml/day) might be needed. Increase in stepwise fashion (e.g. 250 micrograms steps).
	Children 5-10yrs	Starting dose: 1,000 micrograms (4ml)	Once daily	
	Children >10 yrs	Starting dose: 1,500 micrograms (6ml)	Once daily	

Instructions for use

This medicine is for oral use only.

1. Open the bottle: Press downward on the cap and turn it counter-clockwise (Figure 1).
2. **First time use only:** A Press-In Bottle Adapter (PIBA) is provided with the oral syringe. This is the device that gets inserted into the neck of the bottle to make it easier to withdraw the solution using the oral syringe. If the PIBA is not already in place, remove the PIBA and 5ml oral syringe from the plastic overwrap. With the bottle on a flat surface, insert the PIBA into the bottle neck while keeping the PIBA's flat surface facing up and pressing on it (Figure 2).
3. Push the syringe plunger to the bottom of the barrel of the syringe (toward its tip) to remove excess air. Attach the syringe to the PIBA with a slight twisting motion (Figure 3).
4. Invert the bottle (with the syringe attached) and fill the syringe with the liquid by pulling the syringe plunger down to just beyond the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 4). Remove air bubbles from the syringe by pushing the plunger up to the appropriate graduation mark.
5. Return the bottle to an upright position with the syringe still in the PIBA/bottle (Figure 5).
6. Remove the syringe from the bottle/PIBA (Figure 6).
7. Empty the contents of the syringe directly into the mouth by pushing the syringe plunger to the bottom of the syringe barrel (Figure 7).
8. Rinse the syringe by drawing water into the syringe and pushing the syringe plunger to the bottom of the syringe barrel, at least three times (Figure 8).
9. Replace the cap on the bottle (leaving the PIBA in place in the bottle neck) (Figure 9).



Figure 1

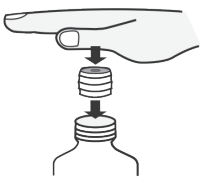


Figure 2

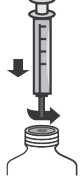


Figure 3



Figure 4

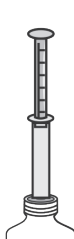


Figure 5

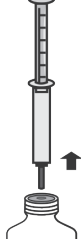


Figure 6



Figure 7

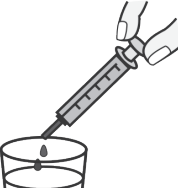


Figure 8

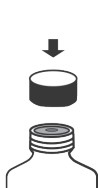


Figure 9

If you use more Colchicine oral solution than you should

If you use more Colchicine oral solution than you are supposed to or for example if a child has taken any of this medicine by accident, there is a risk of overdose. You should contact your doctor, pharmacist, nurse or nearest hospital accident and emergency department immediately.

Signs of overdose

- After ingestion of too high a dose of colchicine, early symptoms of overdose appear only after several hours. These symptoms include a burning sensation in throat, stomach and skin, nausea, vomiting, abdominal cramps, and bloody diarrhoea which may lead to a too low pH value of the blood, dehydration, lowering of blood pressure and shock.
- Subsequently, 24-72 hours after ingestion of too high a dose the following life-threatening complications may occur: consciousness disorder with possible delusions (delirium), coma, symptoms of paralysis, respiratory depression, fluid retention in the lungs, kidney damage, a shortage of blood and cardiac arrest.
- About 7 days after ingestion of too high a dose a temporary increase of white blood cells (leukocytosis) and hair loss may occur.

If you forget to use this medicine

Do not take a double dose to make up for a forgotten dose.

If you forget to take a dose, take another as soon as you remember. If it is almost time for your next dose, do not take the missed dose at all and continue with your prescribed dosing regimen. Always check with your doctor, pharmacist or nurse if you are not sure.

If you stop using this medicine

When you suddenly stop taking this medicine, the symptoms that you suffered from before starting treatment may recur. Always talk to your doctor if you are considering stopping colchicine treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible Side Effects

Like all medicines, colchicine can cause side effects, although not everybody gets them.

Stop taking this medicine and immediately contact a doctor or the nearest hospital accident and emergency department if you get any of the following side effects:

- Nausea, vomiting, abdominal pain and diarrhoea. The frequency of these side effects is common (may affect up to 1 in 10 people).
- Weakness of the muscles (myopathy), red to brown discolouration of urine (rhabdomyolysis), pain in muscle, fatigue. The frequency of these side effects is not known (cannot be estimated from the available data).
- Infection with symptoms such as high fever, severe throat ache and a sore mouth (bone marrow depression with agranulocytosis, pancytopenia, neutropenia, thrombocytopenia, leukopenia) and serious form of anaemia (aplastic anaemia). The frequency of these side effects is not known (cannot be estimated from the available data).
- Hepatotoxicity (liver damage), high transaminases levels. The frequency of these side effects is not known (cannot be estimated from the available data).
- Kidney problems (impaired kidney function). The frequency of these side effects is not known (cannot be estimated from the available data).
- Skin irritations such as urticaria, maculopapular rash, erythema, oedema. The frequency of these side effects is rare (may affect up to 1 in 1000 people).

In addition, the following side effects have been reported:

Frequency unknown (cannot be estimated from the available data):

- Hair loss, rash.
- Sore throat.
- Neuropathy (nerve disease), inflammation of the nerves which can cause pain, numbness and sometimes an impaired nerve function.
- Vitamin B12 deficiency.

The frequency of these side effects is rare (may affect up to 1 in 1000 people).

- Reduction of the number of sperm cells in the seminal fluid or complete absence of sperm cells in the seminal fluid.
- Absence of menstrual periods during a period of 6 months or longer and the occurrence of pain and/or cramps during menstruation.

Children and adolescents up to 18 years of age

No data is available on the effect of long-term colchicine use in children and adolescents up to 18 years of age.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Colchicine oral solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after ‘EXP’. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

Once opened, use within 75 days.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What this medicine contains

The active substance is colchicine. Each 1ml of oral solution contains 250 micrograms colchicine.

The other ingredients are sodium methyl parahydroxybenzoate (E219), citric acid, sodium citrate, sucralose, glycerol (E422), orange flavour ((flavouring preparation, natural flavouring substance, 1,2-Propylene glycol (E 1520), alpha-Tocopherol (E 307)) and purified water.

What Colchicine oral solution looks like and contents of the pack

Colchicine is a clear, colourless solution to nearly colourless liquid, free from visible foreign particles.

This medicine is available in a 75ml amber glass bottle with a white high-density polyethylene (HDPE) child-proof and tamper evident cap.

The product is supplied with a low-density polyethylene (LDPE) plastic plug that is able to fit on the bottle and for accurate dosing a LDPE oral syringe, graduated in 0.1ml steps up to 5ml.

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This leaflet was last revised in February 2026.

Other sources of information

The text only version may be available in large print, Braille or audio CD.
For further information call emc accessibility on 0800 198 5000.
The product code for this leaflet is: PL 35533/0239

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Version no:	3.9
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A/W software:	Indesign CC



Black