

Colchicine tablets 1 mg

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care worker or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or health care worker.

In this leaflet:

1. What Colchicine tablets 1 mg is and what it is used for
2. What you need to know before you take Colchicine tablets 1 mg
3. How to take Colchicine tablets 1 mg
4. Possible side effects
5. How to store Colchicine tablets 1 mg
6. Further information

1. WHAT COLCHICINE TABLETS 1 MG ARE WHAT IT IS USED FOR

Colchicine 1 mg tablet 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

Colchicine is used, in adults, in the short-term treatment of acute gout, so called gout attacks, and to prevent gout from recurring.

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.

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

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2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE COLCHICINE TABLETS 1 MG

Do not use Colchicine 1 mg Tablets

- if you are allergic to colchicine or any of the other ingredients of this medicine
- 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 Colchicine Tablets and a dose that causes symptoms of medicine intoxication; this means that even a little too high a dose can cause acute signs of medicine intoxication. If you get symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking Colchicine Tablets and immediately contact your doctor.

Talk to your doctor or pharmacist 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

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

You should have regular blood tests to monitor any changes.

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

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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.

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

Other medicines and Colchicine Tablets:

Tell your doctor or pharmacist 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 adversely affect your liver or kidney function. In this case, contact your doctor.

If Colchicine Tablets 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 or pharmacist if you are taking:

- erythromycin, telithromycin and clarithromycin (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 intoxication. If possible, do not use these kind of antibiotics during the period that you are being treated with colchicine. If no alternative treatment is available, your doctor may reduce the dose of colchicine and keep under surveillance;
- Ketoconazole, itraconazole, voriconazole (anti-fungal). 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 inhibitor agent used to treat HIV). 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);
- ciclosporine (medicine used to reduce the body's resistance to infection by suppressing the immune system).

Also tell your doctor or pharmacist 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

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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 certain 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). The uptake of vitamin B12 from the gastrointestinal tract may be reduced by colchicine;

Colchicine Tablets 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 or pharmacist 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 Tablets treatment for gout. If, nevertheless, pregnancy occurs during this time period, genetic counselling should be tasked.

Pregnancy:

Treatment of gout:

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

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Breast-feeding:

The active substance colchicine passes into your breast milk. Colchicine Tablets should not be used in breast-feeding women with gout.

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 tasked.

Driving and using machines

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

Colchicine Tablets contains lactose

Colchicine tablets contain lactose monohydrate.

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE COLCHICINE TABLETS 1 MG:

Always use this medicine exactly as your doctor has told you. Check with your doctor or 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 or pharmacist if you feel that the effect of Colchicine tablets is too strong or not strong enough.

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Use in adults

Use in Gout

Treatment of an acute gout attack:

The recommended dose is 0.5mg (500 micrograms) two to three times daily. Your doctor may decide to prescribe an additional 1mg (1000 micrograms) for the first day 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 6 mg of Colchicine Tablets during a course of treatment.

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

Prevention of gout attack:

The recommended dose is 0.5mg-1mg/day (500 - 1000 micrograms) and should be taken in the evening.

Your doctor will tell you how long your treatment with Colchicine Tablets will last.

If you have kidney or liver problems

If you have impaired liver or kidney function the recommended dose is 0.5 mg (500 micrograms) colchicine per day and you should be carefully monitored. If you have severely impaired hepatic or severe renal function you should not use this medicine.

Children and adolescents

Colchicine Tablets should not be used for the treatment of gout in children and adolescents.

Mode of administration

Tablets should be swallowed whole with a glass of water.

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If you use more Colchicine tablets than you should

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

Signs of intoxication

- After ingestion of too high a dose of Colchicine tablets 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 diarrhea 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 Colchicine tablets

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 or pharmacist if you are not sure.

If you stop taking Colchicine Tablets

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 consider to stop taking colchicine.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking Colchicine Tablets 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 cramps 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 discoloration of urine (rhabdomyolysis). Pain in muscle, fatigue. The frequency of these side effects is uncommon (may affect up to 1 in 100 people)
- Infection with symptoms such as high fever, severe throat ache and a sore mouth and serious form of anemia (aplastic anemia). The frequency of these side effects is rare (may affect up to 1 in 1,000 people)

In addition, the following side effects are known:

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

- Hair loss, rash
- Reduction of the number of sperm cells in the seminal fluid or complete absence of sperm cells in the seminal fluid
- Sore throat
- Neuropathy (nerve disease), inflammation of the nerves which can cause pain, numbness and sometimes an impaired nerve function
- Absence of menstrual periods during a period of 6 months or longer and the occurrence of pain and/or cramps during menstruation
- Vitamin B12 deficiency

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- Liver damage

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

5. HOW TO STORE Colchicine tablets 1 mg

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

Store in the original container protected from light.

Do not use Colchicine tablets after the expiry date which is stated on the blister and carton as EXP or EXP date. The expiry date refers to the last day of that month.

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.

This leaflet does not contain all the information about your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.

6. FURTHER INFORMATION

What Colchicine tablets 1 mg tablet contains

The active ingredient in this product is Colchicine. Each Colchicine 1 MG tablets contains 1MG of colchicine.

The other ingredients are Microcrystalline Cellulose, Lactose Monohydrate, Crospovidone, Purified Water, Magnesium Stearate, Instacoat Universal White In House.

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What Colchicine tablets 1 mg tablet like and contents of the pack

White to off white round shaped biconvex film coated tablets debossed with “42 “ on one side and “L” on the other side.

Colchicine tablets are packed in blister of comprising of PVC/PVDC with Al lidding foil.

Each pack contains 30. Not all pack sizes may be marketed.

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