

Package leaflet: Information for the user

Colchicine 500 microgram Tablets

Colchicine

Read all of this leaflet carefully before you start using 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What **Colchicine Tablets** is and what it is used for
2. What you need to know before you use **Colchicine Tablets**
3. How to use **Colchicine Tablets**
4. Possible side effects
5. How to store **Colchicine Tablets**
6. Contents of the pack and other information

1. What Colchicine Tablets is and what it is used for

The name of your medicine is Colchicine. Colchicine is an anti-gout agent. In adults, colchicine is used to treat gout attacks. They are also used to prevent gout flare-ups when treatment is started with other drugs, such as allopurinol, probenecid, and sulfinpyrazone.

In adults and children, this medication is indicated in Familial Mediterranean Fever for the prophylaxis of attacks and prevention of amyloidosis. Familial Mediterranean Fever leads to intermittent attacks of high temperature, pain, and other factors. Treatment for this is under specialised medical care.

2. What you need to know before you use Colchicine Tablets

Do not take Colchicine:

- if you are allergic to colchicine or any of the other ingredients of this medicine (listed in section 6).
- if you have severe blood disorder.
- if you are pregnant.
- if you are breastfeeding.
- if you are a woman of childbearing age, unless you are using effective contraception.
- if you have severe kidney or liver problems.
- if you are undergoing haemodialysis.
- if you have kidney or liver problems and you are taking certain medicines (see 'Other medicines and Colchicine').
- if you are under 12 years of age (unless under specialised treatment for Familial Mediterranean Fever).

If you are not sure whether any of the above apply to you, talk to your doctor or pharmacist before taking Colchicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Colchicine if you:

- are elderly and weak.
- have problems with your heart, kidneys, liver or digestive system.
- have a blood disorder.

Colchicine can be toxic so it is important that you do not exceed the dose prescribed by your doctor.

There is only a slight difference between an effective dose of colchicine and an overdose. Therefore, if you get symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking Colchicine and immediately contact your doctor (see also section 4 'Possible side effects').

Colchicine can cause a serious decrease in bone marrow function leading to a decrease in certain white blood cells (agranulocytosis), a decrease in red blood cells and pigment (aplastic anaemia) and/or a low blood platelet count (thrombocytopenia). 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 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').

Children and adolescents

Only children diagnosed with Familial Mediterranean Fever, and under specialised medical care should take Colchicine tablets.

Other medicines and Colchicine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Taking another medicine whilst using Colchicine can affect how colchicine or the other medicine works.

When Colchicine is taken together with any of the following medicines, side effects due to colchicine toxicity are more likely and these can be serious and life-threatening:

- Certain antibiotics such as clarithromycin, erythromycin and telithromycin (used to treat infections).
- Anti-viral drugs such as ritonavir, atazanavir and indinavir (used to treat HIV infection).
- Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis).
- Anti-fungal medicines such as ketoconazole, itraconazole and voriconazole.
- Certain heart medicines such as verapamil and diltiazem.
- Disulfiram (used to help treat alcoholism).

If you are taking any of the above medicines, your doctor may want to adjust your dose of Colchicine or temporarily stop your treatment with Colchicine. If you have liver or kidney problems and you are taking any of the above medicines, you should not take Colchicine.

It is also important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Cimetidine (used to reduce stomach acid), as it may increase the amount of colchicine in your blood.
- Tolbutamide (used to control blood sugar), as it may increase the amount of colchicine in your blood.
- Digoxin (used to treat certain heart conditions) and 'fibrates' (medicines used to lower cholesterol), as they may increase your risk of a muscle disease known as 'rhabdomyolysis'. Taking Colchicine together with ciclosporin or 'statins' also increases your risk of developing this disease.

Talk to your doctor before taking Colchicine if you are taking any medicines that may possibly damage your kidneys, liver or blood. Check with your doctor if you are not sure.

Colchicine may reduce the amount of vitamin B12 that your body can absorb through your gut.

Colchicine with food and drink

Grapefruit juice may increase the amount of colchicine in your blood. Therefore, you should not drink grapefruit juice whilst you are taking Colchicine.

Pregnancy and breast-feeding

You should not take Colchicine if you are pregnant - **talk to your doctor first.**

Colchicine passes into the breast milk. Do not take Colchicine if you are breast-feeding.

If you are pregnant, think you may be pregnant or are planning to have a baby, do not take this medicine.

If you are a woman of childbearing potential, do not take this medicine unless you are using effective contraception.

Driving and using machines

The possibility of drowsiness and dizziness should be taken into account. If affected, do not drive or operate machinery.

Colchicine contains lactose

Colchicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. is essentially 'sodium-free'.

3. How to use Colchicine Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many Colchicine tablets to take, and for how long you should take them.

Colchicine should be swallowed whole with a glass of water.

In cases where swallowing the tablet is considered to be challenging/ not possible, the patient/ carer should have a discussion with their health care professional (HCP) regarding the most appropriate alternative administration.

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ARTWORK DETAIL LABEL

Product	Colchicine 500 microgram tablets			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	160 x 400 mm		Pack	--
New Item Code	1047455	Old Item Code	NA	
Colour Shades	Black	No. of Colours	1	
Change Control No.	NA	Artwork Version	1.0	
Design/Style	Front & Back Printing. To be Supplied in single folding size of 160 x 200 mm.			
Substrate	60 GSM Paper.			
Special Instructions	Printing clarity to be clear & sharp.			
Autocartanator Requirements	Pack insert supply should be as per auto-cartanator. Refer auto-cartanator drawing for instructions.			
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Use in Adults

Dose to treat gout attack:

- The recommended dose is two (2) Colchicine tablets to start, followed by one (1) Colchicine tablet after one (1) hour. No further tablets should then be taken for twelve (12) hours. If necessary, treatment with Colchicine tablets can then resume with a maximum dose of one (1) tablet three times daily until symptoms are relieved.

The course of treatment should end when symptoms are relieved or when a total of twelve (12) Colchicine tablets have been taken. You should not take more than twelve (12) Colchicine tablets as a course of treatment. After completion of a course of Colchicine tablets, you should not start another course for at least three days.

Dose to prevent flare-ups of gout when treatment is started with other drugs:

- The recommended dose is one (1) Colchicine tablet twice daily.

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

Dose in Familial Mediterranean Fever

The recommended dose is two (2) to six (6) Colchicine tablets daily. The daily dose may be taken as a single dose or may be divided over two doses daily (for doses of three (3) to six (6) tablets daily).

If you do not feel better, your doctor may increase the dose of colchicine in a stepwise fashion up to a maximum of six (6) tablets daily. You should be carefully monitored by your doctor for side effects with any increase in the dose of colchicine.

If you have kidney or liver problems

Your doctor may reduce your dose of Colchicine, and you should be carefully monitored for side effects.

Do not take Colchicine if you have severe kidney or liver problems.

Use in children and adolescents:

The **only use in children and adolescents** is for the treatment of **Familial Mediterranean Fever**, while under close medical supervision.

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 posology is based on age. The following daily doses may be given as a single or divided dose twice daily (for doses over 1mg/day);

For children aged under 5 years, the usual dose is one tablet a day, as a single dose.

For children aged 5 years to 10 years, the usual dose is two tablets a day, as a single or divided dose.

For children aged over 10 years, the usual dose is three tablets a day, as a single or divided dose.

Colchicine dosage should be increased in a stepwise fashion (0.25 mg/step) up to a maximum of 2 mg/day (four tablets a day). Any increase of the dose should be monitored closely for adverse effects.

Mode and route of administration

Oral route

Tablet should be swallowed whole with a glass of water.

If you take more Colchicine than you should

If you take more Colchicine than you are supposed to immediately contact your doctor or nearest hospital accident and emergency department. Take this leaflet and any Colchicine tablets you have left with you.

At too high a dose Colchicine can be seriously toxic, even fatal. Early symptoms of overdose (which appear on average after 3 hours but can take longer) may include nausea, vomiting, stomach pain, bloody diarrhoea and low blood pressure.

If you forget to take Colchicine

If you forget to take 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.

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

Do not take Colchicine with a shorter interval than prescribed by your doctor.

If you stop taking Colchicine

Do not stop taking Colchicine without talking to your doctor first.

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.

If you notice any of the following side effects, stop

taking Colchicine and immediately contact a doctor or the nearest hospital accident and emergency department:

- Nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea (see also section 2 'Warnings and Precautions'). These side effects are common (may affect up to 1 in 10 people).
- Symptoms such as fever, inflammation of the mouth, sore throat, prolonged bleeding, bruising or skin problems. These could be signs that you have a serious blood problem as a result of bone marrow depression (see also section 2 'Warnings and Precautions').

The frequency of these side effects is not known (cannot be estimated from the available data).

Other side effects that have been seen (with unknown frequency) are:

- Inflammation of the nerves which can cause pain, weakness, tingling or numbness.
- Nerve damage.
- Gastrointestinal bleeding.
- Liver damage.
- Hair loss.
- Rash.
- Pain or weakness in muscles.
- Abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis).
- Kidney damage.
- Absence of menstrual periods.
- Painful periods.
- Reduced ability to produce sperm (low or zero sperm count).

Additional side effects in children and adolescents

Side effects may be more frequent in this patient group.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: 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 Tablets

Keep the blister in the outer carton, in order to protect from light.

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.

The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Colchicine Tablets contains

- The active substance is colchicine.
- The other ingredients are: Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, magnesium stearate E572, Povidone K-30

What Colchicine Tablets looks like and contents of the pack

Colchicine 500 microgram tablets are white, coloured round shaped tablets debossed with C5 on one side and plain on other side.

Packed in blisters of Alu/PVC/PVDC in 10, 14, 20, 28, 30, 40, 50, 56, 60, 70, 80, 84, 90, 100, 112's pack sizes.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, Metro Centre, Tolpits Lane,
Watford, Hertfordshire,
WD18 9SS United Kingdom

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