

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**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 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.

**What is in this leaflet**

1. What Colchicine Tablets Ph. Eur 0.5 mg and what it is used for
2. What you need to know before you take Colchicine Tablets Ph. Eur 0.5 mg
3. How to take Colchicine Tablets Ph.Eur 0.5 mg
4. Possible side effects
5. How to store Colchicine Tablets Ph.Eur 0.5 mg
6. Contents of the pack and other information

**1. WHAT COLCHICINE TABLETS PH. EUR 0.5 MG ARE AND WHAT IT IS USED FOR**

The name of your medicine is Colchicine Tablets.

The active ingredient, colchicine, in Colchicine Tablets is an anti-gout agent.

Colchicine Tablets are used to treat gout attacks. They are also used to prevent flare-ups of gout when treatment is started with other drugs such as allopurinol, probenecid and sulfinpyrazone.

**2. BEFORE YOU TAKE COLCHICINE TABLETS PH. EUR 0.5 MG**

**Do not take Colchicine Tablets if you:**

- if you are allergic to colchicine or any of the other ingredients of this medicine .
- if you have a severe blood disorder
- if you are pregnant
- if you are breastfeeding

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- 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 .

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

**Warnings and precautions:**

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

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

Colchicine Tablets 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 Tablets and an overdose. Therefore, 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 (see also section 4 ‘Possible side effects’).

Colchicine Tablets 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.

**Other medicines and Colchicine Tablets:**

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

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When Colchicine Tablets are 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 Tablets or temporarily stop your treatment with Colchicine Tablets. If you have liver or kidney problems and you are taking any of the above medicines, you should not take Colchicine Tablets. 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 Tablets together with ciclosporin or ‘statins’ also increases your risk of developing this disease.

Talk to your doctor before taking Colchicine Tablets 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 Tablets may reduce the amount of vitamin B12 that your body can absorb through your gut.

**Colchicine Tablets 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 Tablets.

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**Pregnancy and breast-feeding and fertility:**

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. Colchicine passes into breast milk. If you are breast-feeding, do not take this medicine.

**Driving and using machines:**

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

**Colchicine Tablets contain lactose:**

**‘Colchicine Tablets contain lactose’.** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Colchicine Tablets.

Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**3. HOW TO TAKE COLCHICINE TABLETS PH. EUR 0.5 MG**

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 Tablets should be swallowed whole with a glass of water.

**Use in adults:**

Dose to treat gout attack:

- The recommended dose is 2 Colchicine Tablets to start followed by 1 Colchicine Tablet after 1 hour. No further tablets should then be taken for 12 hours. If necessary, treatment with Colchicine Tablets can then resume with a maximum dose of 1 tablet three times daily until symptoms are relieved. The course of treatment should end when symptoms are relieved or when a total of 12 Colchicine Tablets have been taken. You should not take more than 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:

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- The recommended dose is one Colchicine Tablet twice daily. Your doctor will tell you how long your treatment with Colchicine Tablets will last.
- If you have kidney or liver problems
- Your doctor may reduce your dose of Colchicine Tablets, and you should be carefully monitored for side effects.
- Do not take Colchicine Tablets if you have severe kidney or liver problems.
- If you take more Colchicine Tablets than you should
- If you take more Colchicine Tablets than you are supposed to, contact your doctor or nearest hospital accident and emergency department immediately. Take this leaflet and any Colchicine Tablets you have left with you.
- At too high a dose Colchicine Tablets 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 Tablets
- 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. Do not take a double dose to make up for a forgotten tablet. Do not take Colchicine Tablets with a shorter interval than prescribed by your doctor.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines Colchicine Tablets can cause side effects, although not everybody gets them. If you notice any of the following side effects, stop taking Colchicine Tablets and immediately contact a doctor or the nearest hospital accident and emergency department:

- Nausea (feeling sick), vomiting (being sick), stomach pain and diarrhea.

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.

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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)

**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 national reporting systems listed below.

**5. HOW TO STORE COLCHICINE TABLETS PH. EUR 0.5 MG****Store below 30°C.**

Do not use this medicine after the expiry date which is stated on the carton after EXP. 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.

**6. FURTHER INFORMATION****What Colchicine Tablets contain**

- The active substance is colchicine.

Each film coated tablet contains:

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Colchicine Ph. Eur..... 0.5 mg

The other ingredients are Microcrystalline Cellulose, Lactose Monohydrate, Crospovidone, Magnesium Stearate, Instacoat Universal Brown

**What Colchicine Tablets looks like and contents of the pack**

Colchicine 500 microgram tablets are Brown coloured, round shaped, beveled edge, biconvex, film coated tablets, debossed with “I1” on one side and plain on other side.

HDPE container pack of 30 /100 tablets .Such 1 container in a carton along with pack insert.

Alu/ white opaque PVC/PVdC Blister of 10 tablets, such 1/3/10 blisters in a carton along with pack insert.

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