1. What Colchicine Tablets are and what they are used for

The name of your medicine is Colchicine Tablets. The active ingredient, colchicine, is in Colchicine Tablets. 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. What you need to know before you take Colchicine Tablets

Do not take Colchicine Tablets:

- 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 are pregnant.
- If you are breastfeeding.
- If you are a woman of childbearing potential and you are taking certain medicines (see ‘Other medicines and Colchicine Tablets’).
- If you are pregnant, think you may be pregnant or are planning to have a baby.
- If you are breastfeeding.
- If you are undergoing haemodialysis.
- If you have kidney or liver problems and you are taking certain medicines (see ‘Other medicines and Colchicine Tablets’).
- If you are not sure whether any of the above apply to you, talk to your doctor or pharmacist before taking Colchicine Tablets.

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

Driving and using machines

Colchicine Tablets may reduce the amount of vitamin B12 that your body can absorb through your gut. Check with your doctor if you are not sure.

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

- Tolbutamide (used to control blood sugar), as it may increase the amount of colchicine in your blood
- Cimetidine (used to reduce stomach acid), as it may increase the amount of colchicine in your blood
- Other anti-fungal medicines such as ketoconazole, itraconazole and voriconazole
- Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis)
- Anti-viral drugs such as ritonavir, atazanavir and indinavir (used to treat HIV infection)
- Certain antibiotics such as clarithromycin, erythromycin and telithromycin (used to treat infections)

When Colchicine Tablets are taken together with any of the following medicines, side effects due to colchicine toxicity are more likely and can be more severe. It is important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Lactase deficiency
- Cystic fibrosis
- Allopurinol, probenecid and sulfinpyrazone
- Acetazolamide (used to control blood sugar), as it may increase the amount of colchicine in your blood

Taking Colchicine Tablets can affect how they or the other medicine works.

Other medicines and Colchicine Tablets

Tell your doctor or pharmacist if you are taking any other medicines, even those bought without a prescription. Taking another medicine whilst you are taking Colchicine Tablets can affect how they or the other medicine works.

3. How to take 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.

Neutral code not required on the leaflet artworks
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:
• 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 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)

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.

United Kingdom
Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Malta
ADR Reporting
www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colchicine Tablets

Keep this medicine out of the sight and reach of children.
• Do not take Colchicine Tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
• Do not take Colchicine Tablets if you notice that they are showing signs of deterioration such as discoloration.
• Do not store above 25°C
• Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and further information

What Colchicine Tablets contains
The active ingredient in Colchicine Tablets is Colchicine. Each tablet contains 500 micrograms of colchicine (on a dried weight basis).

The other ingredients are lactose, maize starch, stearic acid and purified talc.

What Colchicine Tablets look like and the contents of the pack
Colchicine Tablets are white to pale-yellow in colour and are either unmarked or marked CP on one face. Colchicine Tablets are available in plastic (polypropylene or polyethylene) containers of 100 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK
Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Other formats
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

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<td>Colchicine 500 microgram tablets</td>
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This is a service provided by the Royal National Institute of Blind People.
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