

PACKAGE LEAFLET: INFORMATION FOR THE USER

COLCHICINE 500 MICROGRAM TABLETS

Colchicine

Read all of this 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 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Colchicine Tablets are and what they are used for
2. Before you take Colchicine Tablets
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1. WHAT COLCHICINE TABLETS ARE AND WHAT THEY ARE 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

Do not take Colchicine Tablets if you are:

- allergic to colchicine or any of the other ingredients of Colchicine Tablets (see list under 'What Colchicine Tablets contain')
- pregnant
- under 12 years of age
- undergoing haemodialysis
- suffering from severe kidney impairment
- suffering from any severity of kidney or liver impairment and taking the following drugs:
 - clarithromycin, erythromycin or telithromycin (used to treat infections)
 - ritonavir, atazanavir or indinavir (anti-viral drugs, used to treat HIV infection)
 - ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis)
 - ketoconazole or itraconazole (used to treat fungal infections)
 - verapamil (used to treat high blood pressure or angina)
 - quinidine (used to treat abnormal heart rhythms).

Take special care with Colchicine Tablets if you:

- are elderly (aged 65 years or older)
- feel exhausted and worn out
- have problems with your heart, kidneys, liver or digestive system
- are breast-feeding
- have a blood disorder.

If you have any doubts about whether you should take these tablets then discuss things more fully with your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, as taking another medicine whilst you are taking Colchicine Tablets can affect how they or the other medicine works.

In particular, tell your doctor if you are taking any of the medicines listed in the previous section, as your colchicine dose may need to be changed or the tablets stopped temporarily.

If you are taking a drug called a statin (used to lower cholesterol) you may be at greater risk of side effects. If you get muscle pain or weakness on this combination then speak to your doctor immediately.

You may need to take extra vitamin B₁₂ if you have to take Colchicine Tablets in high doses or for a long time.

Pregnancy and breast-feeding

You should not take Colchicine Tablets if you are pregnant or trying to become pregnant without first discussing this with your doctor.

Colchicine passes into your breast milk. Do not take Colchicine Tablets if you are breast-feeding without talking to your doctor first.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Colchicine Tablets should not affect your ability to drive or operate machinery.

Important information for patients with an intolerance to some sugars

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.

3. HOW TO TAKE COLCHICINE TABLETS

Always take Colchicine Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow your Colchicine Tablets whole with a glass of water.

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

For adults for the treatment of gout:

- The usual adult dose for the treatment of gout is two Colchicine Tablets at the start of treatment followed by one Colchicine Tablet every two to three hours until relief of pain is obtained.
- If you are sick or have diarrhoea you should stop taking Colchicine Tablets and tell your doctor.
- You should not take more than 12 Colchicine Tablets as a course of treatment (your doctor will advise you).
- You should wait three days before starting another course of Colchicine Tablets.

For adults for prevention of flare-ups of gout:

- The usual adult dose for prevention of flare-ups of gout is two to three Colchicine Tablets daily.
- Your doctor will decide which dose is best for you.

For elderly patients or patients with other problems

Elderly patients or patients with other problems, especially kidney problems, will need lower or less frequent doses.

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.

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 missed one.

4. POSSIBLE SIDE EFFECTS

Like all medicines Colchicine Tablets can cause side effects, particularly when treatment is first started, although not everybody gets them.

If you experience any of the following symptoms, **stop taking Colchicine Tablets immediately and contact a doctor or the nearest hospital accident and emergency department:**

- a feeling of burning or rawness in the mouth and throat making swallowing difficult
- feeling or being sick
- diarrhoea with blood in it
- severe stomach pain
- being unable to pass water.

Side effects that are rare include:

- 'pins and needles'
- muscle loss
- muscle cramps or weakness
- hair loss
- blood disorders
- inhibition of spermatogenesis (the inability to produce sperm).

If high doses of Colchicine Tablets are taken

High doses of Colchicine Tablets can cause diarrhoea, rashes or affect the kidneys or liver.

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

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 reach and sight 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 discolouration.
- 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. FURTHER INFORMATION

What Colchicine Tablets contain

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 Limited, 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:

Product name	Reference number
Colchicine 500 microgram Tablets	29831/0055

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised 07/2015.

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