

PACKAGE LEAFLET: INFORMATION FOR THE USER

Colchicine Halewood 500 microgram Tablets

colchicine

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, pharmacist or nurse.
- 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 of the side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Colchicine Halewood 500 microgram Tablets is called 'Colchicine Tablets' in this leaflet.

What is in this leaflet

1. What Colchicine Tablets are and what they are used for
2. What you need to know before you take Colchicine tablets
3. How to take Colchicine Tablets
4. Possible side effects
5. How to store Colchicine Tablets
6. Contents of the pack and other information

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

The active ingredient in Colchicine Tablets is colchicine.

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

In children, Colchicine Tablets are indicated in Familial Mediterranean Fever for relief during attacks and to prevent a build up of proteins from happening.

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 could get pregnant, unless you are using effective contraception
- if you are undergoing haemodialysis
- if you have severe kidney or liver problems
- 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.

Warnings and precautions

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

- are elderly (aged 65 years or older) and weak
- have problems with your heart, kidneys, liver or digestive system
- 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 (see also section 4 'Possible side effects').

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.

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, and for treating psoriasis and rheumatoid arthritis)
- Medicines such as ketoconazole, itraconazole and voriconazole (which are used to treat fungal infections)
- 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’.
- Macrolide antibiotics such as azithromycin (used to treat infections caused by micro-organisms such as bacteria), as it may increase the amount of colchicine in your blood.

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.

Pregnancy and 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.

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

Driving and using machines

Colchicine Tablets can sometimes cause drowsiness and dizziness. If you are affected in this way, do not drive or operate machinery.

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 this medicine.

Colchicine Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

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.

Colchicine Tablets should be swallowed whole with a glass of water. For adults and children who have difficulty swallowing (especially small children), the tablet can be dissolved in a glass of water and drunk immediately.

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 1 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.

Use in children and Adolescents

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 under 5 years of age the recommended 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 over 10 years of age, the usual dose is three tablets a day, as a single or divided dose.

The doctor may gradually adjust the dose, depending upon the reaction of the child, to a maximum of four tablets a day.

This medicine is not suitable for children who require a dose of less than 1 tablet a day.

Route and method of administration

Oral use

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 one 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 or concerns about 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 HPRA Pharmacovigilance, Website: www.hpra.ie; 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.

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the outer carton, pot, label or blister pack after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the pack or tablets look damaged (for example, if the tablets are discoloured).

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. Contents of the pack and other information

What Colchicine Tablets contain

The active substance is colchicine. Each tablet contains 500 micrograms of colchicine.

The other ingredients are lactose monohydrate, maize starch, sodium lauryl sulphate and magnesium stearate.

What Colchicine Tablets looks like and contents of the pack

Colchicine Tablets are white to off-white circular biconvex tablets with 5.5 mm diameter and plain on both sides.

Colchicine Tablets are available in plastic (polypropylene) pots of 100 tablets and in blister packs of 28 or 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Halewood Chemicals (Ireland) Ltd,
North Point House,
North Point Business Park,
New Mallow Road,
Cork, T23 AT2P, Ireland

Manufacturer:

Pharmadox Healthcare Ltd,
KW20A Kordin Industrial Park,
Paola PLA3000,
Malta.

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