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Package Leaflet: Information for the User

## Colchicine 500 microgram tablets

Colchicine

**Important warning!**  
*Do not exceed the recommended dose. Overdosing, including by ignoring interactions, can lead to a fatal, very painful and irreversible poisoning with a fatal outcome. Please refer to Sections 2, 3 and 4 of this package leaflet. The medicinal product must be kept out of reach of others before and after use.*

**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. Do not pass it onto others. It may harm them, even if their symptoms 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:**

- What Colchicine Tablets is and what it is used for
- What you need to know before you use Colchicine Tablet
- How to use Colchicine Tablets
- Possible side effects
- How to store Colchicine Tablets
- Contents of the pack and other information.

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

Colchicine Tablets contains the active substance colchicine. It belongs to the group of anti-gout agents and is used to prevent or treat a gout attack.

*Gout attacks in Adults*

Colchicine is used, in adults, in the short-term treatment of acute gout, so called gout attacks, and to prevent gout from recurring. The concentration of uric acid in blood is increased in gout. This might lead to precipitation of uric acid crystals in the fluid of joints. Colchicine inhibits the resulting inflammatory response.

You must talk to a doctor if you do not feel better or if you feel worse.

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

**Do not use 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 have severe kidney problems
- if you have severe liver problems

**Warnings and Precautions**

There is a slight difference between an effective dose of Colchicine Tablets and a dose that causes symptoms of medicine intoxication, this means that even a little too high a dose can cause acute signs of a medicine intoxication. 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").

Talk to your doctor or pharmacist before using this medicine if one or more of the following situations apply to you or have been applicable in the past.

- If you have problems with your liver or kidneys
- If you have heart or vascular disease
- If you have problems with your gastrointestinal tract
- If you are elderly and weak
- If you have a blood disorder

Colchicine can cause a severe decrease in bone marrow (disappearance of certain white blood cells (agranulocytosis), shortage of blood platelets (thrombocytopenia), decrease in red blood cells and pigment due to lack of production of red blood cells (aplastic anaemia)).

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").

Long-term use of colchicine may lead to a vitamin B<sub>12</sub> deficiency.

**Other medicines and Colchicine tablets:**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Cautious is advised when this product is used together with medicines that may impair your blood count or adversely affect your liver or kidney function. In this case, contact your doctor.

If Colchicine Tablets is taken together with any of the following medicines, side effects due to colchicine toxicity are more likely and these can be very serious. You must talk to your doctor or pharmacist if you are taking:

- erythromycin, telithromycin and clarithromycin (certain antibiotics, medicines used to treat bacterial infections). The use of these kind of antibiotics during the period you are being treated with colchicine may cause medicine intoxication. If possible, do not use these kind of antibiotics during the period that you are being treated with colchicine. If no alternative treatment is available, your doctor may reduce the dose of colchicine and keep under surveillance;
- Ketoconazole, itraconazole, voriconazole (anti-fungal). You should not use these medicines during the period you are being treated with colchicine;
- Ritonavir, atazanavir, amprenavir, saquinavir, nelfinavir, fosamprenavir and indinavir (certain protease inhibitor agent used to treat HIV). You should not use these medicines during the period you are being treated with colchicine;
- Verapamil, quinidine and diltiazem (medicines used to treat heart disease);
- ciclosporine (medicine used to reduce the body's resistance to infection by suppressing the immune system).

Also tell your doctor or pharmacist if you are taking any of the following:

- Taking the following medicines during the period you are being treated with colchicine may cause a serious muscle disease (myopathy) and breakdown of muscle tissue, which is accompanied by muscle cramps, fever and red-brown discolouration of urine (rhabdomyolysis):
  - Simvastatin, fluvastatin or pravastatin (statins, medicines used to lower cholesterol)
  - fibrates (medicines used to lower cholesterol and certain fats in the blood)
  - digoxin (medicine used to treat heart failure and arrhythmias).
- Cimetidine (used to reduce intestinal or gastric ulcers) and tolbutamide (used to lower blood sugar). They can increase the effect of colchicine;
- Vitamin B<sub>12</sub> (cyanocobalamin). The uptake of vitamin B<sub>12</sub> from the gastrointestinal tract may be reduced by colchicine;

**Colchicine tablets with food and drink**

You should not drink grapefruit juice during the period you are being treated with colchicine.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Women of childbearing potential:

*Treatment of gout*

Women of childbearing potential have to use effective contraception during and for at least 3 months following termination of Colchicine Tablets treatment for gout. If, nevertheless, pregnancy occurs during this time period, genetic counselling should be tasked.

Pregnancy:

*Treatment of gout:*

You should not use Colchicine Tablets if you are or may become pregnant. If, nevertheless, pregnancy occurs during the treatment with Colchicine Tablets or within 3 months after termination of treatment, genetic counselling should be tasked.

**Breast-feeding:**

The active substance colchicine passes into your breast milk.

Colchicine Tablets should not be used in breast-feeding women with gout.

Fertility

*Treatment of gout:*

Male patients should not father a child during and for at least 6 months following termination of colchicine therapy. If, nevertheless, pregnancy occurs during this time period, genetic counselling should be tasked.

**Driving and using machines**

No data are available regarding the influence of colchicine on the stability to drive and use machines. However, the possibility of drowsiness and dizziness should be taken into account.

**Colchicine Tablets contains lactose**

Colchicine tablets contains lactose monohydrate. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to use Colchicine Tablets

Always use this medicine exactly as your doctor has told you. Check with your doctor or

pharmacist if you are not sure.

In too high a dose colchicine is potentially toxic, so it is important not to exceed the dose prescribed by your doctor.

Contact your doctor or pharmacist if you feel that the effect of colchicine tablets is too strong or not strong enough

**Use in adults**

*Use in Gout*

*Treatment of an acute gout attack:*

The recommended dose is 0.5mg (500 micrograms) two to three times daily. Your doctor may decide to prescribe an additional 1mg (1000 micrograms) for the first day of treatment. Treatment should end in the event of gastrointestinal symptoms or no effect after 2 to 3 days.

You should not take more than 6mg of Colchicine Tablets during a course of treatment.

After completion of a course of Colchicine Tablets (or other medicine containing colchicine), you should not start another course for at least three days.

*Prevention of gout attack:*

The recommended dose is 0.5mg-1mg/day (500 - 1000 micrograms) and should be taken in the evening. Your doctor will tell you how long your treatment with Colchicine Tablets will last.

*If you have kidney or liver problems*

If you have impaired liver or kidney function the recommended dose is 0.5 mg (500 micrograms) colchicine per day and you should be carefully monitored. If you have severely impaired hepatic or severe renal function you should not use this medicine, see section "Do not take Colchicine Tablets".

**Children and adolescents**

Colchicine Tablets should not be used for the treatment of gout in children and adolescents.

**Mode of administration**

Tablets should be swallowed whole with a glass of water.

**If you use more Colchicine tablets than you should**

If you use more Colchicine Tablets than you are supposed to or for example if a child has taken any tablets by accident, there is a risk of intoxication. You should contact your doctor, pharmacist or nearest hospital accident and emergency department immediately.

Signs of intoxication

- After ingestion of too high a dose of colchicine tablets early symptoms of overdose appear only after several hours. These symptoms include a burning sensation in throat, stomach and skin, nausea, vomiting abdominal cramps, and bloody diarrhea which may lead to a too low pH value of the blood, dehydration, lowering of blood pressure and shock.
- Subsequently, 24 – 72 hours after ingestion of too high a dose the following life-threatening complications may occur: consciousness disorder with possible delusions (delirium), coma, symptoms of paralysis, respiratory depression, fluid retention in the lungs, kidney damage, a shortage of blood and cardiac arrest.
- About 7 days after ingestion of too high a dose a temporary increase of white blood cells (leukocytosis) and hair loss may occur

**If you forget to use Colchicine tablets**

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

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 and continue with your prescribed dosing regimen. Always check with your doctor or pharmacist if you are not sure.

**If you stop taking Colchicine Tablets**

When you suddenly stop taking this medicine, the symptoms that you suffered from before starting treatment may recur. Always talk to your doctor if you consider to stop taking colchicine. 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.

Stop taking Colchicine Tablets and immediately contact a doctor or the nearest hospital accident and emergency department if you get any of the following side effects:

- Nausea, vomiting, abdominal cramps and diarrhoea. The frequency of these side effects is common (may affect up to 1 in 10 people)
- Weakness of the muscles (myopathy), red to brown discoloration of urine (rhabdomyolysis), pain in muscle, fatigue. The frequency of these side effects is uncommon (may affect up to 1 in 100 people)
- Infection with symptoms such as high fever, severe throat ache and a sore mouth and serious form of anemia (aplastic anemia). The frequency of these side effects is rare (may affect up to 1 in 1,000 people)

In addition, the following side effects are known:

Frequency unknown (cannot be estimated from the available data):

- Hair loss, rash
- Reduction of the number of sperm cells in the seminal fluid or complete absence of

sperm cells in the seminal fluid

- Sore throat
- Neuropathy (nerve disease), inflammation of the nerves which can cause pain, numbness and sometimes an impaired nerve function
- Absence of menstrual periods during a period of 6 months or longer and the occurrence of pain and/or cramps during menstruation
- Vitamin B12 deficiency
- Liver damage

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 this medicine out of the sight and reach of children.

Store in the original container protected from light.

Do not use Colchicine tablets after the expiry date which is stated on the blister and carton as EXP or EXP date. The expiry date refers to the last day of that month.

Shelf life after opening the tablet container is 100 days for HDPE bottle pack.

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.

This leaflet does not contain all the information about your medicine. If you have any questions or you are not sure about anything ask your doctor or pharmacist.

### 6. Contents of the pack and other information

**What Colchicine Tablets contains**

The active ingredient in this product is colchicine. Each Colchicine 500 microgram tablet contains 500 microgram of colchicine.

The other ingredients (excipients) are lactose monohydrate, pregelatinised starch, sodium starch glycolate, colloidal anhydrous silica, stearic acid.

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

**Colchicine 500 microgram tablets**

White to off white, biconvex, round uncoated tablets with 'L' debossed on one side and plain on other side. (approximately 5mm diameter & approximately 2.6mm thick)

Colchicine tablets are packed in blister of comprising of PVC/PVDC with Al lidding foil. Each pack contains 10, 14, 20, 28, 30, 40, 56, 60, 84, 90, 98 and 100 tablets Colchicine tablets are packed HDPE bottle with polypropylene child-resistant closure.

Each bottle contains 30 and 100 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

The Marketing Authorisation Holder for your tablet is:

**RIA Generics Limited,**  
36 Ingleby Way,  
Wallington, Surrey SM6 9LR,  
United Kingdom

**Manufacturer:**  
**Wave Pharma Limited**  
4th Floor Cavendish House, 369 Burnt Oak,  
Edgware, Middlesex, HA85AW, UK

**RIA Generics Limited**  
36 Ingleby Way  
Wallington  
SM6 9LR  
United Kingdom

If you would like this leaflet in different format information or want to report any side effects please contact marketing authorisation holder listed above.

If you would like to have any further information or want to report any side effects, please email at [info@riagenerics.com](mailto:info@riagenerics.com).

**This leaflet was last revised in October 2020**