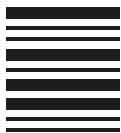


What you need to know about Colchicine Tablets

Please read this leaflet carefully before you start to take your tablets. It contains important information. If you are not sure about anything, or you want to know more, ask your doctor or a pharmacist. Keep this leaflet safe, as you may want to read it again.

Your tablets are called Colchicine Tablets BP and they are part of a group of drugs known as anti-mitotics. The medicine acts by stopping the movement of granulocytes (a type of white blood cell) into a damaged area which is swollen, red and painful (inflamed). This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



What is in this leaflet:

1. What Colchicine is and what it is used for
2. Before you take Colchicine Tablets
3. How to take Colchicine Tablets
4. Possible side effects
5. How to store Colchicine Tablets
6. Further information

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

The active ingredient in Colchicine Tablets is Colchicine. In adults, Colchicine Tablets are used in the short term treatment of gout and to prevent attacks of gout from happening.

Uric acid is one of the body's waste products. In gout, crystals of uric acid are deposited in joints causing pain and inflammation.

Other medicines which are used to treat gout (like allopurinol or uricosuric drugs), take a long time to work and so colchicine can be used together with these drugs at the start of treatment.

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

Familial Mediterranean Fever, is an inherited disease causing pain and swelling in the joints and body organs.

2. Before you take Colchicine Tablets

Do not take Colchicine Tablets if you:

- Think you may be allergic to Colchicine or to any of the other ingredients of Colchicine Tablets. (These are listed in section 6.);
- You have a problem with your blood, e.g. leukaemia;
- You have any problems with your liver;
- You have any problems with your kidneys;
- You have any problems with your heart;
- You have any problems with your digestive system;
- You are pregnant, may become pregnant or are breast feeding.

Please tell your doctor before you start to take Colchicine Tablets if you:

- Have ever had an adverse reaction to Colchicine or to any of the other ingredients of Colchicine Tablets. (These are listed in section 6.);
- Are pregnant, may become pregnant or are breastfeeding;
- Have ever had any problems with your liver or kidneys;
- Are older than 40 years of age;

Are you taking other medicines?

Some medicines can interfere with your treatment. Tell your doctor if you are elderly or debilitated. Tell your doctor if you are taking any of the following:

- You are receiving vitamin B12 injections for anaemia. Colchicine may prevent the absorption of vitamin B12;

- You are taking sympathomimetic drugs (e.g. to treat asthma or a blocked nose);
- You are taking drugs which depress the nervous system (e.g. some drugs used to treat anxiety and sleeping problems);
- You are taking cyclosporin (a drug used to reduce the body's resistance to infection by suppressing the immune system.
- You are taking the antibiotic erythromycin or clarithromycin. These antibiotics can increase the risk of side effects from colchicine.

These tablets contain Lactose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking these tablets.

If you need blood or urine tests, tell the doctor that you are taking Colchicine Tablets, as your tablets may affect the results. Colchicine may decrease the absorption of fat, sodium, potassium, nitrogen, xylose, and also sugars from the stomach and intestine.

Use in children: These tablets are not suitable for children. If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.

3. How to take Colchicine Tablets

Colchicine is potentially toxic so it is important not to exceed the dose prescribed by your doctor.

You must take your tablets exactly as your doctor has told you to. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take and how often. If you are not sure, ask your doctor or pharmacist. Swallow the tablets whole with water.

The following doses are intended as a guide:

ADULTS:

Treating acute gout: The most common dose for the treatment of gout in adults is 1mg (2 tablets) to start then 500mcg (1 tablet) every 4 hours until the pain is better or you feel sick or diarrhoea occurs. Up to 6mg (12 tablets) can be taken altogether. You should not take treatment again until at least 3 days have passed.

To help prevent attacks of gout: 500mcg (1 tablet) each week may be enough, or 500mcg (1 tablet) 2 - 3 times a day.

To prevent gout happening again or to prevent gout at the start of treatment with other medicines (eg. Allopurinol): Take 500mcg (1 tablet) 2-3 times a day.

If you are elderly, or have kidney problems, you may need a lower dose.

CHILDREN:

In children with Familial Mediterranean fever the recommended dose is based on age. The following daily doses may be given as a single dose or divided dose twice daily (for doses over 1mg/day);

- Children less than 5 years of age: 0.5 mg/day
- Children 5 to 10 years of age: 1 mg/day
- Children more than 10 years of age: 1.5 mg/day

Colchicine dosage should be increased in a stepwise fashion (0.25 mg/step) up to a maximum of 2 mg/day. Any increase of the dose should be monitored closely for adverse effects.

If you forget to take a dose at the right time, take it as soon as you remember. Do not take two doses together.

If you take more colchicine tablets than you should; If you take more colchicine tablets than you are supposed to (or if you think a child has swallowed any), **contact your doctor or nearest hospital accident and emergency department immediately.** Take this leaflet and any colchicine tablets you have left with you.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Allergic reactions may occur and could include breathlessness and collapse.

Colchicine may have an effect on the sperm count in men.

Stop taking these tablets and tell your doctor immediately if you get any of the following:

- A fever;
- A sore throat;
- Rashes or ulcers in your mouth and throat;
- Skin colourations;

as this could be a sign that you are not making any white blood cells to fight off infection. If this happens your treatment should be stopped. However this is a rare side effect and occurs most commonly within the first two months of treatment and in patients over the age of 40 who are taking larger doses.

Other side effects are:

- Loss of hair;
- Skin rashes;

- Inflammation of nerves;
- Muscle weakness;
- Numbness especially in the hands and feet;
- No urine production;
- Blood in the urine and bruising;
- Blood changes and kidney damage may occur;
- Bone marrow may become depressed (no blood cells or clot forming cells being made).

If you feel unwell in any other way, tell your doctor as soon as you can.

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 on the MHRA website (www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colchicine Tablets

Store the tablets in their original pack away from direct light. You should store these tablets below 25°C and protected from light. Keep the container tightly closed.

Keep all medicines out of the reach and sight of children.

Do not take the tablets after the expiry date which is printed on the carton and label.

You should take any tablets that are out of date or which you no longer need back to your pharmacist.

6. Further Information

There is one strength of Colchicine Tablets 500 micrograms (mcg). Colchicine Tablets are white and come in packs of 100.

Colchicine Tablets contain the active ingredient Colchicine. Each tablet contains Colchicine 500 micrograms (mcg) (active ingredient); and lactose, starch maize and magnesium stearate (inactive ingredients).

Marketing Authorisation Holder:

RPH Pharmaceuticals AB, Lagervägen 7,
136 50 Jordbro, Sweden.

Manufacturer:

Recipharm Limited, Vale of Bardsley,
Ashton-under-Lyne, Lancashire, OL7 9RR, UK.

Colchicine Tablets are distributed by:

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