

Package leaflet: Information for the user

Colchicine Ria 0.5 mg tablets
Colchicine

Important warning!

Do not exceed the recommended dose. Overdose, including by ignoring interactions, can lead to fatal, very painful, and irreversible poisoning with fatal outcome. Refer to sections 2, 3, and 4 of this leaflet.

The medicine must be kept out of reach of others before and after use.

Read the entire leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Then contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed only for you. It may be harmful to others, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Colchicine Ria tablets and what is this medicine used for?

Colchicine Ria tablets contain the active substance colchicine.

Colchicine belongs to the group of medicines for gout (gout is an inflammation in a joint, with pain). This medicine is used to prevent or treat a gout attack.

In gout, there is too much uric acid in your blood. This can cause uric acid crystals to end up in the fluid of joints. This leads to an inflammatory reaction. This medicine reduces this inflammatory reaction.

In children, this medicine is prescribed for familial Mediterranean fever (FMF, a hereditary disease with fever attacks and attacks of abdominal, chest, or joint pain). This medicine prevents attacks in FMF and unusual deposition of proteins in tissues and organs (amyloidosis).

Is your complaint not getting better, or is it even getting worse? Then contact your doctor.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the substances in this medicine. You can find these substances in section 6.
- Your kidneys are functioning poorly.
- Your liver is functioning poorly.
- You have severe blood disorders.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before taking this medicine:

- if you have problems with your heart, kidneys, liver or digestion,
- if you are elderly and frail,
- if you have a blood disorder.

This medicine can be toxic, so it is important not to take more than the dose prescribed by your doctor.

There is only a small difference between an effective dose of this medicine and an overdose. If you experience symptoms such as a burning sensation in the mouth or throat, nausea, vomiting, abdominal pain, and diarrhea, stop using this medicine and contact your doctor immediately (see also section 4 'Possible side effects').

- if you experience symptoms such as fever, inflammation of the mouth, sore throat, or prolonged bleeding, bruising, or skin problems, stop using this medicine and contact your doctor immediately. These may be signs that you have a serious blood problem, and your doctor may want to perform a blood test immediately (see also section 4 'Possible side effects').
- this medicine can cause your bone marrow to function less effectively (too few white blood cells, making you more susceptible to illness (agranulocytosis)), too few platelets (thrombocytopenia), less hemoglobin and red blood cells because no red blood cells are being produced (aplastic anemia). Aplastic anemia, in particular, carries a high risk of death. Your blood should be regularly monitored.

Children and adolescents up to 18 years

For use in children, this medicine should only be prescribed under the supervision of a medical specialist with the necessary knowledge and experience. There are no data on the effects of long-term use of this medicine in children. This medicine is mainly prescribed for children with familial Mediterranean fever (FMF).

Are you taking any other medicines?

Are you taking any other medicines besides Colchicine Ria tablets, have you recently done so, or is there a possibility that you will take other medicines in the near future? If so, tell your doctor or pharmacist. Using another medicine while taking Colchicine Ria tablets can affect how the tablets work or how the other medicine works.

Be cautious if you are also taking medicines that can alter the blood profile or cause your kidneys or liver to function less effectively.

If you use Colchicine Ria tablets together with any of the medicines listed below, there is an increased risk of side effects due to colchicine poisoning (colchicine toxicity). These side effects can be severe and life-threatening.

Do not use colchicine simultaneously with these medicines:

- certain antibiotics (agents against bacterial infections, e.g., erythromycin and clarithromycin). Using colchicine and these antibiotics simultaneously can lead to colchicine poisoning. If possible, you should not use these medicines at the same time.

If no other treatment is possible, your doctor may lower the dose of colchicine and monitor you;

- antifungal medicines (ketoconazole, itraconazole, voriconazole, posaconazole);
- medicines for treating heart disease (verapamil and diltiazem);
- ritonavir (specific protease inhibitor, medicine for treating the HIV virus);
- ciclosporin (this medicine reduces your body's immune response to infections (an infection is an inflammation caused by bacteria or viruses. The immune response provides protection against diseases).

If you are using any of the above medications, your doctor may adjust your dose of Colchicine Ria tablets or temporarily stop your treatment with Colchicine Ria tablets. If you have liver or kidney problems and are using any of the above medications, you should not use Colchicine Ria tablets.

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

- The use of the following medications while being treated with colchicine can cause severe muscle disease (myopathy) and damage to your muscles (this is called rhabdomyolysis. You may experience muscle pain that does not go away, cramps in your muscles, a weak feeling in your muscles, sometimes urine the color of cola, feeling sick):
Statins, such as simvastatin, fluvastatin, or pravastatin (these are medications used to lower cholesterol),
fibrates (e.g., gemfibrozil, fenofibrate – medications used to lower cholesterol and some fats in the blood),
digoxin (medication for the treatment of heart failure and arrhythmias),
cimetidine (medication for intestinal or stomach ulcers) and tolbutamide (medication that lowers blood sugar). The effect of colchicine can thereby be enhanced,
vitamin B12 (cyanocobalamin). Colchicine can cause vitamin B12 to be less well absorbed from the stomach and intestines.

What should you pay attention to with food and drink?

Do not drink grapefruit juice and do not eat grapefruits when using this medication. Grapefruit juice can increase the amount of colchicine in the blood and can cause poisoning.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medication.

Pregnancy

You should not use this medication if you are pregnant or could become pregnant during treatment for gout or familial Mediterranean fever (FMF). If you do become pregnant during treatment with this medication or within 3 months after ending the treatment, your doctor should provide you with information about the possible occurrence of birth defects. This is called genetic counseling.

Breastfeeding

The active substance colchicine passes into your breast milk.

This medication should not be used by women with gout who are breastfeeding. In women with familial Mediterranean fever (FMF) who are breastfeeding, a decision must be made to either stop breastfeeding or stop the therapy with colchicine, or not to start the treatment. The benefit of breastfeeding for the child and the benefit of treatment for the woman must be weighed against each other.

Fertility

If familial Mediterranean fever (FMF) is not treated, it can also lead to infertility. Therefore, the use of this medication must be weighed against the possible risks. The medication can then be considered if the symptoms are so severe that treatment is necessary.

If colchicine is used for the treatment of acute gout or for the prophylaxis of a gout attack during the initiation of urate-lowering therapy

Male patients should not father a child during and for at least 6 months after ending treatment with colchicine. If a pregnancy occurs during this period, genetic counseling should be provided.

Driving ability and the use of machines

Note: you may become drowsy or dizzy. If you experience this, do not drive and do not operate machines.

Colchicine Ria tablets contain lactose

This medicine contains lactose monohydrate.

Has your doctor told you that you cannot tolerate some sugars? Then contact your doctor before taking this medicine.

3. How do you use this medicine?

Always take this medicine exactly as your doctor has told you. Are you unsure about the correct use?

Your doctor will tell you how much of this medicine you need to take and how long you need to take it.

Colchicine can be toxic. Therefore, it is important not to take more than the prescribed dose.

Gout

Use in adults:

Dosage for a sudden attack of gout:

The recommended dosage is 0.5 mg 2 to 3 times a day. You may first receive a starting dose of 1 mg. The treatment should be stopped if you experience gastrointestinal complaints and if the medicine has no effect after 2 to 3 days.

The course should stop if the symptoms have lessened or if a total dose of 6 mg colchicine has been taken. You must not take more than this during one treatment course.

After a course of this medicine, you should start a new course at least 3 days later.

Dosage for preventing an attack of gout:

The normal dose is 0.5 mg to 1 mg per day, to be taken in the evening.

Familial Mediterranean fever

Use in adults

The recommended dose is 1-3 mg per day. The dose can be administered as a single dose. Are you receiving a dose higher than 1 mg per day? Then it can be divided into two portions throughout the day.

If the symptoms do not decrease, the dose of colchicine should be gradually increased to a maximum of 3 mg per day. With each increase in the daily dose, side effects should be closely monitored.

Use in children and adolescents up to 18 years

In children with familial Mediterranean fever (FMF), the recommended dosage depends on age.

- Children under 5 years: 0.5 mg per day;
- Children between 5 and 10 years old: 1 mg per day;
- Children older than 10 years: 1.5 mg per day.

In children with the disease amyloid nephrosis (unusual deposition of proteins in tissues and organs in the kidneys), the dose may need to be increased to 2 mg per day.

If you have kidney and liver problems

Your doctor may reduce your dose of this medicine; the dose is 0.5 mg colchicine per day and you should be closely monitored for side effects. Do not take this medicine if you have severe kidney or liver problems. See section 2: 'When should you not use this medicine or be extra careful?'

How do you use this medicine and how do you take it?

Oral (by mouth)

The tablet should be taken with a glass of water.

Duration of treatment

Your doctor will tell you how many tablets you should use and how long you may use the tablets.

If you notice that the colchicine tablets are too strong or not strong enough, contact your doctor or pharmacist.

Have you taken too much of this medicine?

If you have used too many Colchicine tablets, contact your doctor or pharmacist immediately.

If you have used too much of this medicine, contact your doctor or the emergency department of the nearest hospital immediately. Take this leaflet and any remaining Colchicine Ria tablets with you. An overdose of this medicine can be very toxic and even fatal. The first symptoms of overdose (which occur on average after 3 hours, but possibly later) may include: nausea, vomiting, abdominal pain, bloody diarrhea, and low blood pressure. About 7 days after ingestion, a temporary increase in white blood cells (leukocytosis) and hair loss may occur.

Have you forgotten to take this medicine?

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

If you have missed a dose, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and take your medicine at your regular time. Do not take this medicine at shorter intervals than prescribed by your doctor. Always contact your doctor or pharmacist if in doubt.

If you stop using this medicine

When you suddenly stop taking this medicine, the symptoms that existed before the start of treatment may reoccur. Always consult your doctor if you are considering stopping.

If you have any further questions about 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 everyone gets them. If you notice any of the following side effects, stop using this medicine and contact a doctor or the emergency department of the nearest hospital immediately:

Nausea (feeling sick), vomiting (being sick), stomach pain, and diarrhea (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 may be signs that you have a serious blood problem as a result of bone marrow depression (see also section 2 "When should you be extra careful with this medicine?"). The frequency of these side effects is not known (cannot be estimated from the available data).

Other side effects that have been observed (with unknown frequency) are:

- Inflammation of the nerves that can cause pain, weakness, tingling, or tingling numbness
- Nerve damage
- Liver damage
- Hair loss
- Rash
- Pain or weakness in the muscles
- Abnormal muscle breakdown that can lead to kidney problems (rhabdomyolysis)

Kidney damage
Absence of menstrual periods
Painful menstruation
Vitamin B12 deficiency
Sore throat

Reduced ability to produce sperm (low or zero sperm count)

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Store in the original packaging to protect from light.

Do not use this medicine after the expiry date. It can be found on the blister pack and the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

This leaflet does not contain all the information about your medicine. If you have questions or doubts, contact your doctor or pharmacist.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is colchicine. Each Colchicine Ria 0.5 mg tablet contains 0.5 mg colchicine.

The other substances (excipients) in this medicine are lactose monohydrate, pregelatinized starch, sodium starch glycolate, colloidal anhydrous silica, stearic acid.

What do Colchicine Ria tablets look like and what is in a package?

Colchicine 0.5 mg tablets

White to off-white, round, biconvex, uncoated tablets with "L" embossed on one side and plain on the other side (approximately 5 mm in diameter and approximately 2.6 mm thick)

Colchicine Ria tablets are packed in PVC/PVDC blister packs with aluminum foil. Each package contains 20, 30, 50, 60, 75, 90, and 100 tablets.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer:

Marketing authorization holder:

RIA Generics Ltd
The Black Church
St. Mary's Place, Dublin 7
D07 P4AX
Ireland

Manufacturer:

RIA Generics Limited
Cube Building, Monahan Road
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Registered under:

Colchicine Ria 0.5 mg tablets RVG 121364

This medicine is registered in EEA member states under the following names

Malta Colchicine 0.5 mg tablets

Spain Colchicina RIA 1 mg comprimidos

Netherlands Colchicine Ria 0.5 mg and 1 mg tablets

This leaflet was last approved in February 2024