

## Colchicine 0.5 mg tablets

### What is Colchicine tablets and what is it used for?

Colchicine tablets contain the active ingredient colchicine.

Colchicine belongs to the group of medicines used for treating gout (a joint inflammation causing pain). This medication is used to prevent or treat a gout attack.

In gout, there is too much uric acid in your blood. This can result in uric acid crystals settling in joint fluid, leading to an inflammatory reaction. This medication reduces this inflammatory reaction.

In children, this medication is prescribed for familial Mediterranean fever (FMF), an inherited disease characterized by fever attacks and episodes of abdominal, chest, or joint pain. This medication prevents FMF attacks and abnormal protein deposition in tissues and organs (amyloidosis).

If your condition does not improve or worsens, contact your doctor.

### When should you not use this medication or use it with extra caution?

#### When should you not use this medication?

- If you are allergic to any of the substances in this medication..
- If your kidneys are not functioning properly.
- If your liver is not functioning properly.
- If you have severe blood abnormalities.

#### When should you use this medication with extra caution?

Contact your doctor or pharmacist before taking this medication:

- If you have problems with your heart, kidneys, liver, or digestive system.
- If you are elderly and weakened,
- If you have a blood disorder.

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

There is only a small difference between an effective dose of this medication 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 medication 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 issues, stop using this medication and contact your doctor immediately. These may be signs that you have a serious blood problem, and your doctor may want to perform blood tests right away (see also section 4 'Possible side effects').

This medication can cause your bone marrow to function less effectively (low white blood cell count, agranulocytosis), low platelet count (thrombocytopenia), decreased blood pigment and red blood cells due to lack of production (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 of age

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

#### Are you taking any other medications?

If you are taking other medications in addition to Colchicine tablets, have taken them recently, or may take other medications in the near future, inform your doctor or pharmacist. The use of another medication while taking Colchicine tablets may affect how the tablets work or how the other medication works.

Be cautious if you are also using medications that can alter blood count or impair kidney or liver function.

If you use Colchicine tablets together with any of the following medications, 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 concurrently with these medications:

Certain antibiotics (agents against bacterial infections, e.g., erythromycin and clarithromycin). Concurrent use of colchicine and these antibiotics can lead to colchicine poisoning. If possible, you should not use these medications at the same time. If no alternative treatment is available, your doctor may reduce the colchicine dose and monitor you;

Antifungal medications (ketoconazole, itraconazole, voriconazole, posaconazole);

Medications for the treatment of heart disease (verapamil and diltiazem);

Ritonavir (specific protease inhibitor, medication for treating the HIV virus).

Cyclosporine (this medication impairs your body's immune response against infections (an infection is an inflammation caused by bacteria or viruses. Immune response provides protection against diseases).

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

Also, inform 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 muscle damage (this is called rhabdomyolysis. You may experience persistent muscle pain, muscle cramps, muscle weakness, sometimes pass urine with the color of cola, feel 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 certain fats in the blood),
- Digoxin (medication for the treatment of heart failure and cardiac arrhythmias),
- Cimetidine (medication for intestinal or stomach ulcers) and tolbutamide (medication that lowers blood sugar). The effect of colchicine can be enhanced as a result,
- Vitamin B12 (cyanocobalamin). Colchicine can reduce the absorption of vitamin B12 from the stomach and intestines.

#### **What should you be aware of regarding food and drink?**

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

**Pregnancy, breastfeeding, and fertility:** Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Contact your doctor before using this medication.

**Pregnancy:** You should not use this medication if you are pregnant or can 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 discontinuation of treatment, your doctor should provide you with information about the potential birth defects. This is called genetic counseling.

**Breastfeeding:** The active substance colchicine passes into your breast milk.

This medication should not be used in women with gout who are breastfeeding.

In women with familial Mediterranean fever (FMF) who are breastfeeding, a decision should be made to either discontinue breastfeeding or discontinue colchicine therapy or not initiate treatment. The benefits of breastfeeding for the child and the benefits of treatment for the woman should be weighed against each other.

**Fertility:** Untreated familial Mediterranean fever (FMF) can also lead to infertility. Therefore, the use of this medication should be weighed against the possible risks. The medication may be considered if the symptoms are severe enough to require treatment.

**Driving ability and the use of machinery:** Caution: you may become drowsy or dizzy. If you experience these symptoms, do not drive or operate machinery.

- Colchicine tablets contain lactose
- This medication contains lactose monohydrate.
- Has your doctor told you that you are intolerant to certain sugars? Then contact your doctor before taking this medication.

#### **How to use this medication?**

Always take this medication exactly as your doctor has told you. If you are unsure about the correct usage, contact your doctor or pharmacist. Your doctor will tell you how much of this medication to take and for how long. Colchicine can be toxic. It is important not to take more than the prescribed dose.

#### **Use in adults:**

**Dosage for an acute gout attack:** The recommended dose is 0.5 mg 2 to 3 times per day. You may initially receive a starting dose of 1 mg. The treatment should be discontinued if you experience gastrointestinal symptoms and if the medication has no effect after 2 to 3 days.

The course of treatment should stop once the symptoms have improved or when a total dose of 6 mg of colchicine has been taken. You should not take more than this during a single course of treatment.

After completing a course of this medication, you should wait at least 3 days before starting a new course.

**Dosage for preventing a gout attack:** The usual dose is 0.5 mg to 1 mg per day, taken in the evening.

**Familial Mediterranean fever:** The recommended dose is 1-3 mg per day. The dose can be administered as a single dose. If you receive a dose higher than 1 mg per day, it can be divided into two doses throughout the day.

If the symptoms do not improve, the colchicine dose should be gradually increased up to a maximum of 3 mg per day. Close monitoring for side effects is necessary with each increase in the daily dose.

## Use in children and adolescents up to 18 years old

- For children with familial Mediterranean fever (FMF), the recommended dosage depends on the age.
- Children younger than 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.

For children with amyloid nephrosis (unusual protein deposition in tissues and organs in the kidneys), the dose may need to be increased up to 2 mg per day.

## If you have kidney and liver problems

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

## How to use this medication and how to take it?

- Oral administration (by mouth)
- The tablet should be taken with a glass of water.

For children under 1 year of age, a colchicine solution can be chosen.

## Duration of treatment

- Your doctor will tell you how many tablets to use and how long you may use the tablets.
- If you notice that the colchicine tablets are too strong or too weak, contact your doctor or pharmacist.

## Did you take too much of this medication?

If you have taken too much of this medication, contact your doctor or the emergency department of the nearest hospital immediately. Take this leaflet and any remaining Colchicine tablets with you. An overdose of this medication can be highly toxic and even fatal. The initial symptoms of overdose (which occur on average after 3 hours but may also occur later) can include nausea, vomiting, abdominal pain, bloody diarrhea, and low blood pressure.

Approximately 7 days after ingestion, a temporary increase in white blood cells (leukocytosis) and hair loss may occur.

## Did you forget to take this medication?

- Do not take a double dose to make up for a missed 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 medication at your regular time. Do not take this medication with a shorter interval than prescribed by your doctor. When in doubt, always contact your doctor or pharmacist.

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

**Possible side effects:** Like any medication, this medication can also have side effects, although not everyone experiences them. If you notice any of the following side effects, stop using this medication immediately and seek medical attention or go to the emergency department of the nearest hospital:

Stomach and intestines Common (occurring in up to 1 in 10 users): Nausea, vomiting, abdominal cramps, and diarrhea.

The frequency of these side effects is unknown (cannot be estimated based on available data), unless otherwise stated.

## Nervous system

**Disorders of the nervous system:** Nerve disease (neuropathy), nerve inflammation accompanied by pain, sensory disturbances, and sometimes impaired nerve function leading to pain (peripheral neuritis).

## Blood vessels

Colchicine can cause severe changes in the bone marrow (bone marrow depression). This leads to changes in blood pressure, insufficient white blood cells (agranulocytosis) accompanied by sudden high fever, severe sore throat, and mouth ulcers, as well as severe anemia (aplastic anemia) and low blood platelets (thrombocytopenia). Platelets are responsible for forming clots.

## Skin

Hair loss, skin rash.

## Urinary tract and kidneys

Reddish-brown discoloration of urine (in case of rhabdomyolysis, which is muscle damage). You may experience persistent muscle pain, muscle cramps, weakness in your muscles, occasional urine with the color of cola, and feeling unwell.

**Skeletal and muscular system**

Muscle disease (myopathy), muscle damage (rhabdomyolysis), muscle pain, fatigue.

**Male and female reproductive organs**

Absence of menstruation for a period of 6 months or more (amenorrhea), experiencing pain and/or cramps during menstruation (dysmenorrhea), fewer sperm cells in seminal fluid (oligospermia), and no sperm cells at all in semen (azoospermia).

**Respiratory system**

Sore throat.

**Nutrition and metabolism**

Insufficient vitamin B12.

**How to store this medication?**

- Keep out of sight and reach of children.
- Store in the original packaging to protect from light.
- Do not use this medication after the expiry date stated on the blister packaging and the box (EXP). The expiry date is indicated as a month and a year. The last day of that month is the expiry date.
- Do not dispose of medications through wastewater or household waste. Ask your pharmacist how to dispose of medications that are no longer needed. These measures will help protect the environment.
- This leaflet does not contain all the information about your medication. If you have any questions or doubts, please contact your doctor or pharmacist.