

Package leaflet: Information for the user

Colchicine Indoco 500 microgram tablets colchicine

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- 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 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

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

1. What Colchicine Indoco is and what it is used for

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

In gout, the concentration of uric acid in the blood is increased. This allows uric acid crystals precipitate in the fluids of joints. Colchicine Indoco inhibits the resulting inflammatory response.

Colchicine Indoco is used in adults:

- For the treatment of acute gout.
- For the prevention of a gout attack during initiation of uric acid lowering therapy.

2. What you need to know before you take Colchicine Indoco

Do not take Colchicine Indoco

- 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 renal impairment
- If you have severe hepatic impairment
- If you are a woman of childbearing potential, unless pregnancy is excluded, for example through effective contraception.

Warnings and precautions

At the first signs of poisoning such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking Colchicine Indoco and immediately contact your doctor. There is a slight difference between the active dose and the dose at which symptoms of poisoning occur.

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.

- o "If you have problems with you liver or kidneys.
- o If you have cardiovascular disease.
- o If you have problems with your gastrointestinal tract.
- o If you are elderly and weak.
- o If you have a blood disorder."

Colchicine can cause a serious reduction in the effect of the bone marrow (disappearance of certain white blood cells from the blood (agranulocytosis), shortage of platelets (thrombocytopenia), decrease in red blood cells and pigment due to lack of production of red blood cells blood cells (aplastic anaemia). You should have regular blood tests to monitor any changes.

If you develop symptoms suggestive of blood count abnormalities such as fever, inflammation of the mouth, sore throat or 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. Blood tests should be carried out straight away.

Other medicines and Colchicine Indoco

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. That is also the case for medicines for which you do not need a prescription. Caution is advised with concomitant use of medicinal products that affect the blood count or negatively affect liver or kidney function,

When Colchicine Indoco 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, psoriasis and rheumatoid arthritis)
- Anti-fungal medicines such as ketoconazole, itraconazole and voriconazole
- Certain heart medicines such as verapamil and diltiazem

If you are taking any of the above medicines, your doctor may want to adjust your dose of Colchicine Indoco or temporarily stop your treatment with Colchicine Indoco . If you have liver or kidney problems and you are taking any of the above medicines, you should not take Colchicine Indoco .

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
- Vitamin B12 (cyanocobalamin), as the intake of vitamin B12 from the gastrointestinal tract may be reduced by colchicine.
- 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.
- Statins such as simvastatin, fluvastatin or pravastatin (medicines used in the lowering cholesterol), fibrates (medicines used to lower cholesterol and some fats in the blood), ciclosporin (anti-

inflammatory immune response) and digoxin (medicine used to treat certain heart conditions) as the use of these agents with colchicine can lead to muscle disease (myopathy) and muscle tissue breakdown, which is associated with muscle cramps, fever and reddish brown discoloration of the urine (rhabdomyolysis).

Colchicine Indoco 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.

Animal studies have shown that colchicine is harmful to the foetus. Do not use this product if you are of childbearing potential, unless effective contraceptive measures are taken. Because colchicine passes into breast milk, Colchicine Indoco should not be used if you are breast-feeding.

Driving and using machines

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

Colchicine Indoco contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dose that is to say essentially 'sodium-free'.

3. How to take Colchicine Indoco

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Adults:

Dosage in an acute gout attack:

The recommended dose is 0.5 mg two to three times a day, Your doctor may decide to prescribe an additional 1 mg for the first day of treatment. Treatment should be stopped if gastrointestinal side effects occur, if there is no effect after 2 to 3 days, or when symptoms are relieved.

Dosage to prevent a gout attack:

The recommended dose is 0.5 mg to 1 mg per day. This should be taken in evening.

Dosage in hepatic or renal impairment

In patients with mild to moderate impaired hepatic or renal function, the recommended dose is 1 tablet (0.5 mg colchicine) per day. If you have severely impaired hepatic or renal function you should not use this medicine, see section "Do not take Colchicine Indoco".

Mode of administration.

Oral use

Take the tablets with a glass of water.

Duration of treatment:

Your doctor will tell you how many tablets to take and for how long you should take the tablets.

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

If you take more Colchicine Indoco than you should

If you take too much Colchicine Indoco, contact your doctor or pharmacist 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, 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: disturbance of consciousness with possible delusions (delirium), coma, paralysis, respiratory depression, cardiac arrest fluid retention in the lungs, kidney damage and a shortage of blood.
- 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 take Colchicine Indoco

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

If you stop using Colchicine Indoco

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.

Overall, the following side effects of colchicine have been reported and mostly resolved after short-term discontinuation or reduction of the dose of colchicine.

Common (may affect up to 1 in 10 people):

- *Stomach and intestines:* Nausea, vomiting, abdominal cramps and diarrhea.

Not known (frequency cannot be estimated from the available data):

- *Nervous system:* Nerve disease (neuropathy), nerve inflammation associated with pain, sensory disturbances and sometimes reduced nerve function (peripheral neuritis).
- *Blood vessels:* Colchicine can cause serious changes in the bone marrow (bone marrow depression), which can cause a change in the blood count such as a lack of white blood cells (agranulocytosis) accompanied by sudden high fever, severe sore throat and mouth sores and anemia (aplastic anemia).
- *Skin:* Hair loss, skin rash.
- *Bladder:* Reddish brown discoloration of the urine (rhabdomyolysis)
- *Skeleton and Muscles:* Disease of the muscles (myopathy), muscle pain, fatigue.
- *Sex organs:* Absence of menstruation for a period of 6 months or more (amenorrhoea), the occurrence of pain and/or cramps during menstruation (dysmenorrhoea), a decrease in number of sperm cells in the seminal fluid (oligospermia) and complete absence of sperm cells in the semen (azoospermia).
- *Hepatobiliary disorders:* 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 www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Colchicine Indoco

- Keep this medicine out of the sight and reach of children.
- This medicine does not require any special temperature storage conditions. 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 carton and blister after 'EXP'. The expiry date refers to the last day of that month.
- 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 Indoco contains

- The active substance is colchicine. Each tablet contains 500 microgram colchicine.

- The other ingredients are :
Lactose monohydrate
Cellulose,microcrystalline
Sodium starch glycolate (Type A)
Magnesium stearate

What Colchicine Indoco looks like and contents of the pack

<Product name> are white to pale yellow, round, tablets, marked with 'C 75' on one side.

<Product name> are available in blisters containing 10, 12, 20, 30, 50, 100, 150 or 200 tablets in blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Indoco Remedies Czech s.r.o.
Třtinová 260/1, Čakovice,
196 00 Praha 9, Czech Republic

Manufacturer

Formula Pharmazeutische und chemische Entwicklungs GmbH
Goerzallee 305 b 14167 Berlin Germany.

MISOM Labs Limited
Malta Life Science Park, LS2.01.06
Industrial Estate, San Gwann, SGN 3000, Malta.

This medicine is authorised in the Member States of the European Economic Area under the following names:

- NL: Colchicine Indoco 0,5 mg, tabletten
- CZ: Colchicine Indoco.
- FI: Colchicine Indoco 500 mikrogrammaa, tabletit.
- DE: Colchicin Indoco 0,5 mg Tabletten
- IE: Colchicine Indoco 500 microgram Tablets
- SK: Colchicine Indoco 0,5 mg tablety
- ES: Colchicine Indoco 0,5 mg comprimidos
- HR: Kolhicin Indoco 0,5 mg tablete

This leaflet was last revised in {month YYYY}

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