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PACKAGE LEAFLET: INFORMATION FOR THE USER

Colchicine Tiofarma 500 microgram Tablets

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 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 is Colchicine Tiofarma and what it is used for
2 What you need to know before you use Colchicine Tiofarma Tablets
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1 WHAT COLCHICINE TIOFARMA TABLETS IS AND WHAT IT IS USED FOR

Colchicine Tiofarma 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.

Familial Mediterranean Fever
In addition, Colchicine Tiofarma Tablets is indicated in Familial Mediterranean Fever to prevent fever attacks and amyloidosis (abnormal precipitation of proteins in tissues and organs).

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 TIOFARMA TABLETS

Do not use Colchicine Tiofarma 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 Tiofarma 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 Tiofarma 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 function (disappearance of certain white blood cells (agranulocytosis), shortage of blood platelets (thrombocytopenia), decrease in red blood cells and pigment due to a 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 B12 deficiency.

Children and adolescents to 18 years
For use in children, colchicine should only be prescribed under the supervision of a medical specialist. No data is available regarding the effect of long-term colchicine use in children.

Other medicines and Colchicine Tiofarma Tablets
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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Caution is advised when this product is used together with medicines that may impair your blood count or negatively influence your liver and kidney function. In this case, contact your doctor.

If Colchicine Tiofarma 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, claritromycin and azithromycin (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. When no other treatment is possible, your doctor may lower the dose of colchicine and keep you under surveillance;
- ketoconazole, itraconazole, voriconazole (anti-fungal medicines). 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 inhibitors used to treat HIV infection). 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).
- ciclosporin (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 some fats in the blood)
  - digoxin (medicine used to treat heart failure and arrhytmias).
- cimetidine (used to reduce intestinal or gastric ulcers) and tolbutamide (used to lower blood sugar). They can increase the effect of colchicine
- vitamin B12 (cyanocobalamin). Absorption of vitamin B12 from the gastrointestinal tract may be reduced by colchicine.

Colchicine Tiofarma 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 Tiofarma 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 Tiofarma Tablets if you are or may become pregnant. If, nevertheless, pregnancy occurs during the treatment with Colchicine Tiofarma Tablets or within 3 months after termination of treatment, genetic counselling should be tasked.

Treatment of FMF:
Since the course of FMF without treatment may also negatively influence pregnancy, the use of Colchicine Tiofarma Tablets during pregnancy should be weighed against the potential risks and may be considered, if clinically needed.

Breast-feeding:
The active substance colchicine passes into your breast milk.
Colchicine Tiofarma Tablets should not be used in breast-feeding women with gout.
In lactating mothers with FMF, a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from colchicine therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

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.

Treatment of FMF:
Since the course of FMF without treatment may also lead to infertility, the use of Colchicine Tiofarma Tablets should be weighed against the potential risks and may be considered, if clinically needed.

Driving and using machines
No data is 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 Tiofarma Tablets contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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Colchicine Tiofarma Tablets contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3 HOW TO USE COLCHICINE TIOFARMA TABLETS

Always use this medicine exactly as your doctor or pharmacist 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 0.5 mg two to three times daily. Your doctor may decide to prescribe an additional 1 mg 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 6 mg of Colchicine Tiofarma Tablets during a course of treatment.
After completion of a course of Colchicine Tiofarma 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 0.5 – 1 mg/day and should be taken in the evening. Your doctor will tell you how long your treatment with Colchicine Tiofarma 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 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 Tiofarma Tablets".

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

Use in Familial Mediterranean Fever
The recommended dose is 1 – 3 mg/day. The daily dose may be taken as a single dose or may be divided over two doses daily (for doses over 1 mg/day).

If you do not feel better, your doctor may increase the dose of colchicine in a stepwise fashion up to a maximum of 3 mg/day. You should be carefully monitored by your doctor for side effects with any increase in the dose of colchicine.

Use in children and adolescents up to 18 years of age
In children with Familial Mediterranean Fever the recommended posology is based on age.
- Children <5 years of age: 0.5 mg/day
- Children 5 to 10 years of age: 1 mg/day
- Children >10 years of age: 1.5 mg/day

In children with amyloid nephropathy it is possible that the dose should be increased to 2 mg/day.

Dosing in impaired liver or kidney function
If you have impaired liver or kidney function the recommended dose will be halved. If you have severely impaired liver or kidney function you should not use this medicine, see section "Do not take Colchicine Tiofarma Tablets".

Mode of administration
Tablets should be swallowed whole with a glass of water.
For children younger than 1 year a colchicine oral solution can be considered.

If you use more Colchicine Tiofarma Tablets than you should
If you use more Colchicine Tiofarma 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 Tiofarma 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 regime. Always check with your doctor or pharmacist if you are not sure.

If you stop using Colchicine Tiofarma 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 stopping 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 Tiofarma Tablets and immediately contact a doctor or the nearest hospital accident and emerceny 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 occurence of pain and/or cramps during menstruation
- Vitamin B12 deficiency
- Liver damage

Children and adolescents up to 18 years of age
No data is available on the effect of long-term colchicine use in children and adolescents up to 18 years of age.

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 the Yellow Card Scheme (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 TIOFARMA TABLETS

- Keep this medicine out of the sight and reach of children.
- Store below 25°C. 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, label and blister after 'EXP'. A month and a year are mentioned there. The expiry date refers to the last day of that month.
- Shelf life after first opening of the tablet container is 6 months.
- 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 Tiofarma Tablets contains
The active substance is colchicine.
The other ingredients are lactose monohydrate, microcrystalline cellulose (E460), sodium starch glycolate and magnesium stearate (E572).

What Colchicine Tiofarma Tablets look like and contents of the pack
Colchicine Tiofarma 500 microgram Tablets are off-white, round tablets with the inscription '0,5' on one side.

Colchicine Tiofarma 500 microgram Tablets are packed in:

- Blister strips with 12 tablets per strip and 1 strip in a carton box, or
- Blister strips with 10 tablets per strip and 3 strips in a carton box, or
- Blister strips with 10 tablets per strip and 10 strips in a carton box, or
- White plastic tablet containers with 250 tablets, in a carton box.

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