

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

COLCHICINE 0,5 mg TRINITY TABLETS

Colchicine

Contains sugar:

Each tablet contains 50,85 mg lactose monohydrate equivalent to 48,31 mg lactose.

Read all of this leaflet carefully because it contains important information for you

COLCHICINE 0,5 mg TRINITY is available without a doctor's prescription, for you to treat a mild illness / maintain your health. Nevertheless, you still need to take COLCHICINE 0,5 mg TRINITY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again;
- Do not share COLCHICINE 0,5 mg TRINITY with any other person;
- Ask your health care provider or pharmacist if you need more information or advice;
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

1. What COLCHICINE 0,5 mg TRINITY is and what it is used for
2. What you need to know before you take COLCHICINE 0,5 mg TRINITY
3. How to take COLCHICINE 0,5 mg TRINITY
4. Possible side effects
5. How to store COLCHICINE 0,5 mg TRINITY
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1. What COLCHICINE 0,5 mg TRINITY is and what it is used for

The active ingredient in COLCHICINE 0,5 mg TRINITY is colchicine.

COLCHICINE 0,5 mg TRINITY is used for the short-term treatment of gout in adults. Gout is a condition in which defective metabolism of uric acid causes painful inflammation of the joints, especially in the smaller bones of the feet and episodes of acute pain.

2. What you need to know before you take [PRODUCT NAME]

Do not take COLCHICINE 0,5 mg TRINITY:

- If you are hypersensitive (allergic) to colchicine or any of the other ingredients of COLCHICINE 0,5 mg TRINITY;
- If you are pregnant or breastfeeding your baby;
- If you are a female of childbearing potential, unless you are using an effective contraceptive;
- If you suffer from serious digestive system, kidney, liver or heart conditions;
- If you are undergoing haemodialysis, a procedure in which a machine filters and cleans your blood instead of your kidneys;
- If you have blood dyscrasias (disorders) a medical condition (haematologic disorders) that may affect the cellular or plasma components of the blood, the bone marrow, or the lymph tissue. Examples of blood dyscrasias include anaemias (decrease in the production of your red blood cells), cancers such as leukaemia's and lymphomas, conditions that cause the blood to clot or bleed too readily, and more. Symptoms of blood disorders include fever, sore throat, bleeding for a longer than usual time, inflammation of your mouth, bruising or abnormal skin rashes and abnormal tiredness (see section 4 Possible side effects);
- If you are taking a medicine called pristinamycin for the treatment of bacterial infections;
- If you have kidney or liver problems and you are taking certain medicines (see Other medicines and COLCHICINE 0,5 mg TRINITY). Examples of these medicines are:

- Medicines used to treat fungal infections such as itraconazole, voriconazole and ketoconazole.
- Medicines used to manage HIV (human immunodeficiency virus) infections such as ritonavir, atazanavir and indinavir.
- Medicine used to suppress your immune system after an organ transplant such as ciclosporin.
- Medicine used to treat high blood pressure such as verapamil and diltiazem.
- Medicine used to treat alcoholism, disulfiram;
- If you are taking a macrolide antibiotic for the treatment of bacterial infection such as clarithromycin, azithromycin and telithromycin.

Warnings and precautions

Take special care with COLCHICINE 0,5 mg TRINITY:

- COLCHICINE 0,5 mg TRINITY is potentially toxic, so it is important not to exceed the dose prescribed by your doctor, pharmacist or nurse. Larger doses may cause severe diarrhoea, gastrointestinal bleeding, skin rashes and kidney damage;
- If you are elderly (≥ 65 years), in a very weakened and infirm state or suffer from cardiac, hepatic, renal or gastrointestinal disease;
- If you suffer from blood disorders. Periodic blood counts should be done if you are receiving long term therapy with COLCHICINE 0,5 mg TRINITY. COLCHICINE 0,5 mg TRINITY can be toxic. It is important that you **do not exceed the recommended dose**. There is only a slight difference between an effective dose of COLCHICINE 0,5 mg TRINITY and an overdose. Therefore, if you get symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking COLCHICINE 0,5 mg TRINITY and immediately contact your doctor;

- You may experience a burning of the skin and throat while taking COLCHICINE 0,5 mg TRINITY. Inform your health care provider immediately if you notice or experience skin rash, sore throat, fever, unusual bleeding, bruising, tiredness or weakness, numbness or tingling;
- You should stop taking [PROUCT NAME] as soon as gout pain has been relieved or at the first sign of nausea, vomiting, stomach pain, or diarrhoea. If your symptoms persist, contact your health care provider immediately.

Children

Do not use COLCHICINE 0,5 mg TRINITY in children.

Other medicines and COLCHICINE 0,5 mg TRINITY

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Also see Do not take COLCHICINE 0,5 mg TRINITY above for medicines that should not be taken together with COLCHICINE 0,5 mg TRINITY

- Medicines used to treat bacterial infections such as clarithromycin, erythromycin, telithromycin and pristinamycin.
- Medicines used to treat fungal infections such as itraconazole, voriconazole and ketoconazole.
- Medicines used to manage HIV (human immunodeficiency virus) infections such as ritonavir, atazanavir and indinavir.
- Medicine used to suppress your immune system after an organ transplant such as ciclosporin.
- Medicine used to treat high blood pressure such as verapamil and diltiazem.
- Medicine used to treat alcoholism, disulfiram.

Tell your doctor if you are taking any of the following:

- Anti-inflammatory medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (medicines used to treat inflammation) e.g., ibuprofen, diclofenac.
- Medicines used to treat neoplasms or cancer (abnormal growths of tissue) as concomitant use may increase the concentration of acid in your blood and decrease the effect of gout therapy.
- COLCHICINE 0,5 mg TRINITY can cause muscle weakness (myopathy) and the breakdown of muscle fibre (rhabdomyolysis) when co-administered with:
 - Medicines used to treat high cholesterol, referred to as statins and fibrates e.g., simvastatin, fluvastatin, pravastatin, atorvastatin, bezafibrate.
 - Digoxin (used to treat certain heart conditions).
 - Medicine used to suppress your immune system after an organ transplant such as ciclosporin.
- Oral blood thinning medications as more frequent INR checks are required. Possible modification of the dosage of the blood thinning treatment is required with COLCHICINE 0,5 mg TRINITY and for 8 days after its cessation may be required.
- Cimetidine (used to reduce stomach acid), as it may increase the amount of colchicine, as contained in COLCHICINE 0,5 mg TRINITY, in your blood.
- Tolbutamide (used to control blood sugar), as it may increase the amount of colchicine in your blood.
- Talk to your doctor before taking COLCHICINE 0,5 mg TRINITY if you are taking any medicines that may possibly damage your kidneys, liver or blood.
- COLCHICINE 0,5 mg TRINITY may reduce the amount of vitamin B12 that your body can absorb through your gut.
- Water tablets such as chlorthalidone, hydrochlorothiazide, indapamide used in the management of high blood pressure.

COLCHICINE 0,5 mg TRINITY with food and drink

Grapefruit juice may increase the amount of colchicine in your blood. Therefore, you should not drink grapefruit juice whilst you are taking COLCHICINE 0,5 mg TRINITY. Do not consume alcohol while taking COLCHICINE 0,5 mg TRINITY.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take COLCHICINE 0,5 mg TRINITY if you are pregnant or breastfeeding your baby.

Women of childbearing potential must use

effective contraception during treatment with COLCHICINE 0,5 mg TRINITY.

Driving and using machines

COLCHICINE 0,5 mg TRINITY may make you feel dizzy. If COLCHICINE 0,5 mg TRINITY affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

It is not always possible to predict to what extent COLCHICINE 0,5 mg TRINITY may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which COLCHICINE 0,5 mg TRINITY affects you.

COLCHICINE 0,5 mg TRINITY contains lactose monohydrate

COLCHICINE 0,5 mg TRINITY contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor, pharmacist or nurse before taking COLCHICINE 0,5 mg TRINITY.

3. How to take COLCHICINE 0,5 mg TRINITY

Do not share medicines prescribed for you with any other person.

Always take COLCHICINE 0,5 mg TRINITY exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

COLCHICINE 0,5 mg TRINITY is potentially toxic, so it is important not to exceed the dose prescribed by your doctor, pharmacist or nurse.

Adults

In acute gout the initial dose is 0,5 mg to 1 mg (i.e., 1 to 2 tablets) by mouth immediately, followed by 0,5 mg (1 tablet) every 2 hours until pain relief is obtained or gastrointestinal symptoms such as vomiting, or diarrhoea occur.

A maximum total treatment course of 6 mg must not be exceeded. The course should not be repeated within 3 days, but 7 days should preferably elapse between courses of gout treatment with COLCHICINE 0,5 mg TRINITY to avoid cumulative toxicity.

COLCHICINE 0,5 mg TRINITY is not a pain medication and should not be used to treat pain from other causes.

Elderly

Use with caution.

Children

COLCHICINE 0,5 mg TRINITY should not be taken by children.

Method of administration

Swallow the tablets whole with water.

Your doctor, pharmacist or nurse will tell you how long your treatment with COLCHICINE 0,5 mg TRINITY will last. Treatment with COLCHICINE 0,5 mg TRINITY should not be repeated within 3 days. If you have the impression that the effect of COLCHICINE 0,5 mg TRINITY is too strong or too weak, tell your doctor, pharmacist or nurse.

If you take COLCHICINE 0,5 mg TRINITY than you should

In the event of overdosage, consult your doctor, pharmacist or nurse. If neither is available, contact the nearest hospital or poison centre.

If you forget to take COLCHICINE 0,5 mg TRINITY

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

4. Possible side effects

COLCHICINE 0,5 mg TRINITY can have side effects.

Not all side effects reported for COLCHICINE 0,5 mg TRINITY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COLCHICINE 0,5 mg TRINITY, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking COLCHICINE 0,5 mg TRINITY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching;
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to COLCHICINE 0,5 mg TRINITY. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Fever;
- Sore throat or difficulty swallowing;
- Rashes or ulcers in mouth or throat;
- Skin rash or skin colourations and bruising;
- Severe nausea, vomiting or stomach pain that persist (even after treatment with COLCHICINE 0,5 mg TRINITY has been stopped);
- Unusual bleeding, bruising, tiredness or weakness, numbness or tingling.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor or health care provider if you notice any of the following:

Frequent:

- Stomach pain;
- Nausea;
- Vomiting;
- Diarrhoea (runny stomach).

Frequency unknown

- Abnormal laboratory test results;
- Decreased bone marrow functioning, leading to abnormal blood cell function;

- Inflammation of the nerves;
- Numbness especially in the hands and feet;
- General damage to veins;
- Gastrointestinal bleeding;
- Liver damage;
- Loss of hair;
- Skin rashes;
- Muscle weakness;
- Kidney damage with abnormal urine production.

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or nurse.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of COLCHICINE 0,5 mg TRINITY.

5. How to store COLCHICINE 0,5 mg TRINITY

Store all medicines out of sight and reach of children.

Store at or below 25 °C (room temperature).

Do not take COLCHICINE 0,5 mg TRINITY after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What COLCHICINE 0,5 mg TRINITY contains

- The active substance is colchicine. Each tablet contains 0,5 mg colchicine.
- The other ingredients are lactose monohydrate, maize starch, magnesium stearate and pre-gelatinized starch.

What COLCHICINE 0,5 mg TRINITY looks like

COLCHICINE 0,5 mg TRINITY is a 5,5 mm, round shallow biconvex white tablet, plain on both sides.

COLCHICINE 0,5 mg TRINITY is packed in High Density Polyethylene (HDPE) containers with polypropylene caps containing 100 or 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd.

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1686


This leaflet was last revised in

28 February 2023

Registration / Application number

SAHPRA Approved PIL
Colchicine 0,5 mg Trinity

Date
2023-02-28


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55/3.3/0336