

COLSYN (COLCHICINE TABLET USP 500 MCG)

Colchicine (0.5 mg)

What is in this leaflet

1. What COLSYN is used for
2. How COLSYN works
3. Before you use COLSYN
4. How to use COLSYN
5. While you are using it
6. Side effects
7. Storage and Disposal of COLSYN
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What COLSYN is used for

COLSYN is used for the relief of acute gout when the dramatic response can be diagnostic. It is also used for the prevention of recurrent gout and to prevent acute attacks during the first few months of treatment with Allopurinol or gout suppressants.

How COLSYN works

Colchicine produces a dramatic response in acute gout probably by reducing the inflammatory reaction to urate crystals. Colchicine also inhibits cell division.

Before you use COLSYN

- When you must not use it
Pregnancy and lactation

Do not take COLSYN if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take COLSYN if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Tell your doctor if you have:

- Hypersensitivity to the active substance or to any of the excipients.
- Blood dyscrasias.
- Pregnancy.
- Breastfeeding.
- Childbearing potential unless using effective contraceptive measures.
- Severe renal impairment.

- Severe hepatic impairment.
- Undergoing haemodialysis.
- Renal or hepatic impairment who are taking a P-glycoprotein (P-gp) inhibitor or a strong CYP3A4 inhibitor.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Potential risk of severe drug interactions, including death, in certain individual treated with:

- Clarithromycin (Antibiotic)
- Cyclosporin (prevent organ rejection in people who have received organ transplant)
- Erythromycin (Antibiotic)
- Calcium Channel Antagonists (such as Verapamil and Diltiazem)
- Telithromycin (Antibiotic)
- Ketoconazole (Antifungal)
- Itraconazole (Antifungal)
- HIV protease inhibitors
- Nefazodone (Antidepressant)

Avoid consuming grapefruit and grapefruit juice while using Colchicine.

How to use COLSYN

- How much to use

Treatment of acute gout attack:

1 mg (2 tablets) to start followed by 500 micrograms (1 tablet) after 1 hour.

No further tablets should be taken for 12 hours.

After 12 hours, treatment can resume if necessary with a maximum dose of 500 micrograms (1 tablet) every 8 hours until symptoms are relieved.

The course of treatment should end when symptoms are relieved or when a total of 6 mg (12 tablets) has been taken.

No more than 6 mg (12 tablets) should be taken as a course of treatment.

After completion of a course, another course should not be started for at least 3 days (72 hours).

Prophylaxis of gout attack during initiation of therapy with allopurinol and uricosuric drugs:

500 micrograms twice daily.

The treatment duration should be decided after factors such as flare frequency, gout duration and the presence and size of tophi have been assessed.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking COLSYN for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Overdose may cause burning feeling in stomach, throat or skin, vomiting, convulsions, diarrhoea, fever, muscle weakness, fluid in the lungs, respiratory depression or kidney failure.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are

COLSYN (COLCHICINE TABLET USP 500 MCG)

Colchicine (0.5 mg)

taking COLSYN.

Tell your doctor immediately if you become pregnant while taking this medication.

- **Things you must not do**

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give COLSYN to anyone else, even if they have the same symptoms or conditions as you.

- **Things to be careful of**

- Colchicine is potentially toxic so it is important not to exceed the dose prescribed by a physician with the necessary knowledge and experience. Colchicine has a narrow therapeutic window. The administration should be discontinued if toxic symptoms such as nausea, vomiting, abdominal pain, diarrhoea occur.

Colchicine may cause severe bone marrow depression (agranulocytosis, aplastic anaemia, thrombocytopenia). The change in blood counts may be gradual or very sudden. Aplastic anaemia in particular has a high mortality rate. Periodic checks of the blood picture are essential. If patients develop signs or symptoms that could indicate a blood cell dyscrasia, such as fever, stomatitis, sore throat, prolonged bleeding, bruising or skin disorders, treatment with Colchicine should be immediately discontinued and a full haematological investigation should be conducted straight away.

Colchicine should be given with great care in case of:

- Liver or renal impairment.
- Cardiovascular disease.
- Gastrointestinal disorders.
- Elderly and debilitated patients.
- Patients with abnormalities in blood counts.

Patients with liver or renal impairment should be carefully monitored for adverse effects of Colchicine.

Co-administration with P-gp inhibitors and/or moderate or strong CYP3A4 inhibitors will increase the exposure to Colchicine, which may lead to Colchicine induced toxicity including fatalities. If treatment with a P-gp

inhibitor or a moderate or strong CYP3A4 inhibitor is required in patients with normal renal and hepatic function, a reduction in Colchicine dosage or interruption of Colchicine treatment is recommended.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take this medicine.

Side effects

Like all medicines, COLSYN can cause side effects, although not everybody gets them.

Side effects are usually diarrhoea, nausea, vomiting and abdominal pain are often the first signs of toxicity. Bone marrow depression with lowered white blood cell count, low blood platelet count and bone marrow failure have occurred on prolonged treatment as have nerve damage, muscle weakness and rashes, and baldness.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of COLSYN

- **Storage**

Keep out of reach of children
Store at temperatures not exceeding 30 C.
Protect from light

- **Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- **What it looks like**

White, round, biconvex, uncoated tablets plain on both sides.

Ingredients

- Active ingredient
- Colchicine

- Inactive ingredients

Lactose Monohydrate, Microcrystalline Cellulose, Maize Starch, PVP K30, Purified Talc, Colloidal Anhydrous Silica & Magnesium Stearate

- **MAL number:**

MAL22096029ACZ

Manufacturer

XL LABORATORIES PVT. LTD.
E-1223, Phase-I Extn, (Ghatal) RIICO Indl. Area,
Bhiwadi-301019, Rajasthan, India.

Product Registration Holder

Unimed Sdn. Bhd.,
No 53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara, 52200, Kuala Lumpur, Malaysia

Date of revision

10/01/2023

Serial Number:

NPRA (R2) 21/145