COLCHICINE- colchicine tablet
Direct Rx

Colchicine

1.1 Gout Flares

Colchicine tablets are indicated for prophylaxis and the treatment of acute gout flares.

- Prophylaxis of Gout Flares: Colchicine tablets are indicated for prophylaxis of gout flares.
- Treatment of Gout Flares: Colchicine tablets are indicated for treatment of acute gout flares when taken at the first sign of a flare.

1.2 Familial Mediterranean Fever (FMF)

Colchicine tablets are indicated in adults and children four years or older for treatment of familial Mediterranean fever (FMF).

The long-term use of colchicine is established for FMF and the prophylaxis of gout flares, but the safety and efficacy of repeat treatment for gout flares has not been evaluated. The dosing regimens for colchicine tablets are different for each indication and must be individualized.

The recommended dosage of colchicine tablets depends on the patient's age, renal function, hepatic function and use of coadministered drugs [see DOSAGE AND ADMINISTRATION (2.4, 2.5, 2.6)].

Colchicine tablets are administered orally without regard to meals.

Colchicine tablets are not an analgesic medication and should not be used to treat pain from other causes.

2.1 Gout Flares

Prophylaxis of Gout Flares

The recommended dosage of colchicine tablets for prophylaxis of gout flares for adults and adolescents older than 16 years of age is 0.6 mg once or twice daily. The maximum recommended dose for prophylaxis of gout flares is 1.2 mg/day.

An increase in gout flares may occur after initiation of uric acid-lowering therapy, including pegloticase, febuxostat and allopurinol, due to changing serum uric acid levels resulting in mobilization of urate from tissue deposits. Colchicine tablets are recommended upon initiation of gout flare prophylaxis with uric acid-lowering therapy. Prophylactic therapy may be beneficial for at least the first six months of uric acid-lowering therapy.

Treatment of Gout Flares

The recommended dose of colchicine tablets for treatment of a gout flare is 1.2 mg (two tablets) at the first sign of the flare followed by 0.6 mg (one tablet) one hour later. Higher doses have not been found to be more effective. The maximum recommended dose for treatment of gout flares is 1.8 mg over a 1-hour period. Colchicine tablets may be administered for treatment of a gout flare during prophylaxis at doses not to exceed

1.2 mg (two tablets) at the first sign of the flare followed by 0.6 mg (one tablet) one hour later. Wait 12 hours and then resume the prophylactic dose.

2.2 FMF

The recommended dosage of colchicine tablets for FMF in adults is 1.2 mg to 2.4 mg daily.

Colchicine tablets should be increased as needed to control disease and as tolerated in increments of 0.3 mg/day to a maximum recommended daily dose. If intolerable side effects develop, the dose should be decreased in increments of 0.3 mg/day. The total daily colchicine tablets dose may be administered in one to two divided doses.

2.3 Recommended Pediatric Dosage

Prophylaxis and Treatment of Gout Flares

Colchicine tablets are not recommended for pediatric use in prophylaxis or treatment of gout flares.

FMF

The recommended dosage of colchicine tablets for FMF in pediatric patients 4 years of age and older is based on age. The following daily doses may be given as a single or divided dose twice daily:

•
Children 4 to 6 years: 0.3 mg to 1.8 mg daily
•
Children 6 to 12 years: 0.9 mg to 1.8 mg daily
•
Adolescents older than 12 years: 1.2 mg to 2.4 mg daily

2.4 Dose Modification for Coadministration of Interacting Drugs

Concomitant Therapy

Coadministration of colchicine tablets with drugs known to inhibit CYP3A4 and/or P-glycoprotein (P-gp) increases the risk of colchicine-induced toxic effects (Table 1). If patients are taking or have recently completed treatment with drugs listed in Table 1 within the prior 14 days, the dose adjustments are as shown in the table below [see DRUG INTERACTIONS (7)].

Table 1. Colchicine Tablets Dose Adjustment for Coadministration with Interacting Drugs if No Alternative Available*

*
For magnitude of effect on colchicine plasma concentrations [see CLINICAL PHARMACOLOGY (12.3)]
†
Patients with renal or hepatic impairment should not be given colchicine tablets in conjunction with strong CYP3A4 or P-gp inhibitors [see CONTRAINDICATIONS (4)]
‡
When used in combination with Ritonavir, see dosing recommendations for strong CYP3A4 inhibitors [see CONTRAINDICATIONS (4)]

Strong CYP3A4 Inhibitors†

Gout Flares

Noted or Anticipated Outcome

Prophylaxis of Gout Flares

Treatment of Gout Flares

FMF

Drug

Original Intended Dosage

Adjusted Dose

Original Intended Dosage

Adjusted Dose

Original Intended Dosage

Adjusted Dose

Atazanavir

Clarithromycin

Darunavir/

Ritonavir‡

Indinavir

Itraconazole

Ketoconazole

Lopinavir/

Ritonavir

Nefazodone

Nelfinavir

Ritonavir

Saquinavir

Telithromycin

Tipranavir/

Ritonavir

Significant increase in colchicine plasma levels; fatal colchicine toxicity has been reported with clarithromycin, a strong CYP3A4 inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other strong CYP3A4 inhibitors

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

1.2 mg

(2 tablets) followed by 0.6 mg (1 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

0.6 mg

(1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 1.2 mg - 2.4 mg

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

Moderate CYP3A4 Inhibitors

Gout Flares

Note or Anticipated Outcome

Prophylaxis of Gout Flares

Treatment of Gout Flares

FMF

Drug

Original Intended Dosage

Adjusted Dosage

Original Intended Dosage

Adjusted Dosage

Original Intended Dosage

Adjusted Dosage

Amprenavir

Aprepitant

Diltiazem

Erythromycin

Fluconazole

Fosamprenavir (prodrug of Amprenavir)

Grapefruit juice

Verapamil

Significant increase in colchicine plasma concentration is anticipated. Neuromuscular toxicity has been reported with diltiazem and verapamil interactions.

0.6 mg twice a day

0.6 mg once a day

0.3 mg twice a day or 0.6 mg once a day

0.3 mg once a day

1.2 mg

(2 tablets) followed by 0.6 mg (1 tablet)

1 hour later. Dose to be repeated no earlier than 3 days.

1.2 mg

(2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 1.2 mg - 2.4 mg

Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)

P-gp Inhibitors

Gout Flares

Note or Anticipated Outcome

Prophylaxis of Gout Flares

Treatment of Gout Flares

FMF

Drug

Original Intended Dosage

Adjusted Dosage

Original Intended Dosage

Adjusted Dosage

Original Intended Dosage

Adjusted Dosage

Cyclosporine

Ranolazine

Significant increase in colchicine plasma levels; fatal colchicine toxicity has been reported with cyclosporine, a P-gp inhibitor. Similarly, significant increase in colchicine plasma levels is anticipated with other

P-gp inhibitors.

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

1.2 mg

(2 tablets) followed by 0.6 mg

(1 tablet)

1 hour later. Dose to be repeated no earlier than 3 days.

0.6 mg

(1 tablet) x

1 dose. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 1.2 mg - 2.4 mg

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

Table 2. Colchicine Tablets Dose Adjustment for Coadministration with Protease Inhibitors

Protease Inhibitor

Clinical Comment

w/ Colchicine - Prophylaxis of Gout Flares

w/o Colchicine – Treatment of Gout Flares

w/Colchicine – Treatment of FMF

Atazanavir

sulfate

(Reyataz)

Patients with renal or hepatic impairment should not be given colchicine with Reyataz.

Original

dose

Adjusted

dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Darunavir (Prezista)

Patients with renal or hepatic impairment should not be given colchicine with Prezista/ritonavir.

Original dose

Adjusted dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Fosamprenavir (Lexiva) with Ritonavir

Patients with renal or hepatic impairment should not be given colchicine with Lexiva/ritonavir.

Original dose

Adjusted dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Fosamprenavir (Lexiva)

Patients with renal or hepatic impairment should not be given colchicine with Lexiva/ritonavir

Original dose

Adjusted dose

1.2 mg (2 tablets) x 1 dose. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 1.2 mg (may be given as 0.6 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg twice a day or 0.6 mg once a day

0.3 mg once a day

Indinavir (Crixivan)

Patients with renal or hepatic impairment should not be given colchicine with Crixivan.

Original dose

Adjusted dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Lopinavir/

Ritonavir

(Kaletra)

Patients with renal or hepatic impairment should not be given colchicine with Kaletra.

Original dose

Adjusted dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Nelfinavir mesylate (Viracept)

Patients with renal or hepatic impairment should not be given colchicine with Viracept.

Original dose

Adjusted dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Ritonavir (Norvir)

Patients with renal or hepatic impairment should not be given colchicine with Norvir.

Original dose

Adjusted dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Saquinavir mesylate (Invirase)

Patients with renal or hepatic impairment should not be given colchicine with Invirase/ritonavir.

Original dose

Adjusted dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Tipranavir (Aptivus)

Patients with renal or hepatic impairment should not be given colchicine with Aptivus/ritonavir.

Original dose

Adjusted dose

0.6 mg (1 tablet) x 1 dose, followed by 0.3 mg (1/2 tablet) 1 hour later. Dose to be repeated no earlier than 3 days.

Maximum daily dose of 0.6 mg (may be given as 0.3 mg twice a day)

0.6 mg twice a day

0.6 mg once a day

0.3 mg once a day

0.3 mg once every other day

Treatment of gout flares with colchicine tablets is not recommended in patients receiving prophylactic dose of colchicine tablets and CYP3A4 inhibitors.

2.5 Dose Modification in Renal Impairment

Colchicine dosing must be individualized according to the patient's renal function [see USE IN SPECIFIC POPULATIONS (8.6)].

Clcr in mL/minute may be estimated from serum creatinine (mg/dL) determination using the following formula:

[Dosing Calculation]

Gout Flares

Prophylaxis of Gout Flares

For prophylaxis of gout flares in patients with mild (estimated creatinine clearance [Clcr] 50 to 80 mL/min) to moderate (Clcr 30 to 50 mL/min) renal function impairment, adjustment of the recommended dose is not required, but patients should be monitored closely for adverse effects of colchicine. However, in patients with severe impairment, the starting dose should be 0.3 mg/day and any increase in dose should be done with close monitoring. For the prophylaxis of gout flares in patients undergoing dialysis, the starting doses should be 0.3 mg given twice a week with close monitoring [see CLINICAL PHARMACOLOGY (12.3), USE IN SPECIFIC POPULATIONS (8.6)].

Treatment of Gout Flares

For treatment of gout flares in patients with mild (Clcr 50 to 80 mL/min) to moderate (Clcr 30 to 50 mL/min) renal function impairment, adjustment of the recommended dose is not required, but patients should be monitored closely for adverse effects of colchicine. However, in patients with severe impairment, while the dose does not need to be adjusted for the treatment of gout flares, a treatment course should be repeated no more than once every two weeks. For patients with gout flares requiring repeated courses, consideration should be given to alternate therapy. For patients undergoing dialysis, the total recommended dose for the treatment of gout flares should be reduced to a single dose of 0.6 mg (one tablet). For these patients, the treatment course should not be repeated more than once every two weeks [see CLINICAL PHARMACOLOGY (12.3), USE IN SPECIFIC POPULATIONS (8.6)].

Treatment of gout flares with colchicine tablets is not recommended in patients with renal impairment who are receiving colchicine tablets for prophylaxis.

FMF

Caution should be taken in dosing patients with moderate and severe renal impairment and in patients undergoing dialysis. For these patients, the dosage should be reduced [see CLINICAL PHARMACOLOGY (12.3)]. Patients with mild (Clcr 50 to 80 mL/min) and moderate (Clcr 30 to 50 mL/min) renal impairment should be monitored closely for adverse effects of colchicine tablets. Dose reduction may be necessary. For patients with severe renal failure (Clcr less than 30 mL/min), start with 0.3 mg/day; any increase in dose should be done with adequate monitoring of the patient for adverse effects of colchicine [see USE IN SPECIFIC POPULATIONS (8.6)]. For patients undergoing dialysis, the total recommended starting dose should be 0.3 mg (half tablet) per day. Dosing can be increased with close monitoring. Any increase in dose should be done with adequate monitoring of the patient for adverse effects of colchicine [see CLINICAL PHARMACOLOGY (12.3), USE IN SPECIFIC POPULATIONS (8.6)].

2.6 Dose Modification in Hepatic Impairment

Gout Flares

Prophylaxis of Gout Flares

For prophylaxis of gout flares in patients with mild to moderate hepatic function impairment, adjustment of the recommended dose is not required, but patients should be monitored closely for adverse effects of colchicine. Dose reduction should be considered for the prophylaxis of gout flares in patients with severe hepatic impairment [see USE IN SPECIFIC POPULATIONS (8.7)].

Treatment of Gout Flares

For treatment of gout flares in patients with mild to moderate hepatic function impairment, adjustment of the recommended dose is not required, but patients should be monitored closely for adverse effects of colchicine. However, for the treatment of gout flares in patients with severe impairment, while the dose does not need to be adjusted, a treatment course should be repeated no more than once every two weeks. For these patients, requiring repeated courses for the treatment of gout flares, consideration should be given to alternate therapy [see USE IN SPECIFIC POPULATIONS (8.7)].

Treatment of gout flares with colchicine tablets is not recommended in patients with hepatic impairment who are receiving colchicine tablets for prophylaxis.

FMF

Patients with mild to moderate hepatic impairment should be monitored closely for adverse effects of colchicine. Dose reduction should be considered in patients with severe hepatic impairment [see USE IN SPECIFIC POPULATIONS (8.7)].

CLOSE

Colchicine Tablets USP, 0.6 mg — purple color, film-coated, capsule shaped tablets debossed with ‘ [logo] 372’ on one side and score line on the other side of the tablet.

Patients with renal or hepatic impairment should not be given colchicine tablets in conjunction with P-gp or strong CYP3A4 inhibitors (this includes all protease inhibitors except fosamprenavir). In these patients, life-threatening and fatal colchicine toxicity has been reported with colchicine taken in therapeutic doses.

16.1 How Supplied

Colchicine Tablets USP, 0.6 mg are purple colored, film-coated, capsule shaped tablets debossed with ‘Stylized Y 372’ on one side and score line on the other side of the tablet.

Bottles of 30 NDC 43598-372-30

Bottles of 100 NDC 43598-372-01

Bottles of 1,000 NDC 43598-372-10

16.2 Storage

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Protect from light.

DISPENSE IN TIGHT, LIGHT-RESISTANT CONTAINER.

Advise the patient to read the FDA-approved patient labeling (MEDICATION GUIDE).

Dosing Instructions: Patients should be advised to take colchicine tablets as prescribed, even if they are feeling better. Patients should not alter the dose or discontinue treatment without consulting with their doctor. If a dose of colchicine tablets is missed:

- For treatment of a gout flare when the patient is not being dosed for prophylaxis, take the missed dose as soon as possible.
- For treatment of a gout flare during prophylaxis, take the missed dose immediately, wait 12 hours, then resume the previous dosing schedule.
- For prophylaxis without treatment for a gout flare, or FMF, take the dose as soon as possible and then return to the normal dosing schedule. However, if a dose is skipped the patient should not double the next dose.

Fatal Overdose: Instruct patient that fatal overdoses, both accidental and intentional, have been reported in adults and children who have ingested colchicine. Colchicine tablets should be kept out of the reach of children.

Blood Dyscrasias: Patients should be informed that bone marrow depression with agranulocytosis, aplastic anemia and thrombocytopenia may occur with colchicine tablets.

Drug and Food Interactions: Patients should be advised that many drugs or other substances may interact with colchicine tablets and some interactions could be fatal. Therefore, patients should report to their healthcare provider all of the current medications they are taking and check with their healthcare provider before starting any new medications, particularly antibiotics. Patients should also be advised to report the use of nonprescription medication or herbal products. Grapefruit and grapefruit juice may also interact and should not be consumed during colchicine tablets treatment.

Neuromuscular Toxicity: Patients should be informed that muscle pain or weakness, tingling or numbness in fingers or toes may occur with colchicine tablets alone or when it is used with certain other drugs. Patients developing any of these signs or symptoms must discontinue colchicine tablets and seek medical evaluation immediately.

Infertility: Advise males of reproductive potential that colchicine tablets may rarely and transiently impair fertility [see USE IN SPECIFIC POPULATIONS (8.3)].

CLOSE

Colchicine Tablets, USP

(KOL-chi-seen)

for oral use

Read the Medication Guide that comes with colchicine tablets before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about colchicine tablets when you start taking it and at regular checkups.

What is the most important information that I should know about colchicine tablets?

Colchicine tablets can cause serious side effects or death if levels of colchicine are too high in your body.

- Taking certain medicines with colchicine tablets can cause your level of colchicine to be too high, especially if you have kidney or liver problems.
- Tell your healthcare provider about all your medical conditions, including if you have kidney or liver problems. Your dose of colchicine tablets may need to be changed.
- Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements.
- Even medicines that you take for a short period of time, such as antibiotics, can interact with colchicine tablets and cause serious side effects or death.
- Talk to your healthcare provider or pharmacist before taking any new medicine.
- Especially tell your healthcare provider if you take:
  - atazanavir sulfate (Reyataz)
  - cyclosporine (Neoral, Gengraf, Sandimmune)
  - fosamprenavir (Lexiva) with ritonavir
  - indinavir (Crixivan)
  - ketoconazole (Nizoral)
  - nefazodone (Serzone)
  - ritonavir (Norvir)
  - telithromycin (Ketek)
  - clarithromycin (Biaxin)
  - darunavir (Prezista)
  - fosamprenavir (Lexiva)
  - itraconazole (Sporanox)
  - lopinavir/ritonavir (Kaletra)
  - nelfinavir mesylate (Viracept)
  - saquinavir mesylate (Invirase)

- tipranavir (Aptivus)

Ask your healthcare provider or pharmacist if you are not sure if you take any of the medicines listed above. This is not a complete list of all the medicines that can interact with colchicine tablets.

- Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.
- Keep colchicine tablets out of the reach of children.

What are colchicine tablets?

Colchicine tablets are a prescription medicine used to:

- prevent and treat gout flares in adults
- treat familial Mediterranean fever (FMF) in adults and children age 4 or older

Colchicine tablets are not a pain medicine, and it should not be taken to treat pain related to other conditions unless specifically prescribed for those conditions.

Who should not take colchicine tablets?

Do not take colchicine tablets if you have liver or kidney problems and you take certain other medicines. Serious side effects, including death, have been reported in these patients even when taken as directed. See “What is the most important information that I should know about colchicine tablets?”

What should I tell my healthcare provider before starting colchicine tablets? See “What is the most important information that I should know about colchicine tablets?”

Before you take colchicine tablets, tell your healthcare provider about all your medical conditions, including if you:

- have liver or kidney problems.
- are pregnant or plan to become pregnant. It is not known if colchicine tablets will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are a male with a female partner who can become pregnant. Receiving treatment with colchicine tablets may be related to infertility in some men that is reversible when treatment is stopped.
- are breastfeeding or plan to breastfeed. Colchicine passes into your breast milk. You and your healthcare provider should decide if you will take colchicine tablets while breastfeeding. If you take colchicine tablets and breastfeed, you should talk to your child’s healthcare provider about how to watch for side effects in your child.

Tell your healthcare provider about all the medicines you take, including ones that you may only be taking for a short time, such as antibiotics. See “What is the most

important information that I should know about colchicine tablets?”

Do not start a new medicine without talking to your healthcare provider.

Using colchicine tablets with certain other medicines, such as cholesterol-lowering medications and digoxin, can affect each other, causing serious side effects. Your healthcare provider may need to change your dose of colchicine tablets. Talk to your healthcare provider about whether the medications you are taking might interact with colchicine tablets and what side effects to look for.

How should I take colchicine tablets?

- Take colchicine tablets exactly as your healthcare provider tells you to take it. If you are not sure about your dosing, call your healthcare provider.
- Colchicine tablets can be taken with or without food.
- If you take too many colchicine tablets, go to the nearest hospital emergency room right away.
- Do not stop taking colchicine tablets even if you start to feel better, unless your healthcare provider tells you.
- Your healthcare provider may do blood tests while you take colchicine tablets.
- If you take colchicine tablets daily and you miss a dose, then take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time.
- If you have a gout flare while taking colchicine tablets daily, report this to your healthcare provider.

What should I avoid while taking colchicine tablets?

Avoid eating grapefruit or drinking grapefruit juice while taking colchicine tablets. It can increase your chances of getting serious side effects.

What are the possible side effects of colchicine tablets?

Colchicine tablets can cause serious side effects or even cause death. See “What is the most important information that I should know about colchicine tablets?”

Get medical help right away if you have:

- Muscle weakness or pain
- Numbness or tingling in your fingers or toes
- Unusual bleeding or bruising
- Increased infections
-

Feel weak or tired

- Pale or gray color to your lips, tongue or palms of your hands
- Severe diarrhea or vomiting

Gout Flares: The most common side effect of colchicine tablets in people who have gout flares is diarrhea.

FMF: The most common side effects of colchicine tablets in people who have FMF are abdominal pain, diarrhea, nausea and vomiting.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of colchicine tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store colchicine tablets?

- Store colchicine tablets at room temperature between 20° to 25°C (68° to 77°F).
- Keep colchicine tablets in a tightly closed container.
- Keep colchicine tablets out of the light.

Keep colchicine tablets and all medicines out of the reach of children.

General Information about colchicine tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use colchicine tablets for a condition for which it was not prescribed. Do not give colchicine tablets to other people, even if they have the same symptoms that you have. It may harm them. This Medication Guide summarizes the most important information about colchicine tablets. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about colchicine tablets that is written for healthcare professionals.

What are the ingredients in colchicine tablets?

Active Ingredient: colchicine.

Inactive Ingredients: FD&C BLUE #2, FD&C RED #40, hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, polydextrose, pregelatinized starch, sodium starch glycolate, titanium dioxide and triacetin.

For more information, call Dr. Reddy’s Laboratories, Inc. at 1-888-375-3784.

Rx Only

Distributor:
Dr. Reddy’s Laboratories Inc.,
Princeton, NJ 08540

Made in India

This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised: 03/2021

COLCHICINE

colchicine tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-331(NDC:43598-372)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
COLCHICINE (UNII: SML2Y3J35T) (COLCHICINE - UNII:SML2Y3J35T)	COLCHICINE	0.6 mg

Inactive Ingredients

Ingredient Name	Strength
TRIACETIN (UNII: XHX3C3X673)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	purple	**Score**	2 pieces
Shape	CAPSULE	**Size**	8mm
Flavor		**Imprint Code**	Y372
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-331-03	3 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209876	03/01/2022	

Labeler - Direct Rx (079254320)

Registrant - Direct Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct Rx		079254320	repack(72189-331)

Revised: 1/2025 Direct Rx