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## MEDICATION GUIDE

### Colchicine tablets (KOL-chi-seen)

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 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:

<ul style="list-style-type: none"><li>• atazanavir sulfate (Reyataz)</li><li>• cyclosporine (Neoral, Gengraf, Sandimmune)</li><li>• fosamprenavir (Lexiva) with ritonavir</li><li>• indinavir (Crixivan)</li></ul>	<ul style="list-style-type: none"><li>• clarithromycin (Biaxin)</li><li>• darunavir (Prezista)</li><li>• fosamprenavir (Lexiva)</li><li>• itraconazole (Sporanox)</li><li>• lopinavir/ritonavir (Kaletra)</li></ul>
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<ul style="list-style-type: none"> <li>• ketoconazole (Nizoral)</li> <li>• nefazodone (Serzone)</li> <li>• ritonavir (Norvir)</li> <li>• telithromycin (Ketek)</li> </ul>	<ul style="list-style-type: none"> <li>• nelfinavir mesylate (Viracept)</li> <li>• saquinavir mesylate (Invirase)</li> <li>• tipranavir (Aptivus)</li> </ul>
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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.

- 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 much 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 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or Chartwell RX, LLC. at 1-845-232-1683 or go to [www.chartwellpharma.com](http://www.chartwellpharma.com).

### **How should I store Colchicine tablets?**

- Store colchicine tablets at room temperature between 68°F and 77°F (20°C and 25°C).
- 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:** carnauba wax, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate and Opadry-II 40L500004 Purple (Polydextrose, Hypromellose USP (3mPas), Hypromellose USP (6mPas), Triacetin, Hypromellose USP (50mPas), FD&C Blue # 2/ Indigo carmine AL 3% - 5%, FD&C Red #40 / Allura Red AC Aluminium lake 15 – 17%, Macrogol / PEG NF (8000), Titanium Dioxide).

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