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Medication Guide
Colchicine (kol′ chi seen)
Capsules, for oral use

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

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

- Taking certain medicines with colchicine capsules 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 capsules may need to be changed.
- Even medicines that you take for a short period of time, such as antibiotics, can interact with colchicine capsules and cause serious side effects or death.

What are colchicine capsules?

Colchicine capsules are a prescription medication used to prevent gout flares in adults.
It is not known if colchicine capsules are safe and effective for the treatment of:

- acute gout flares

Colchicine capsules are not a pain medicine and it should not be taken to treat pain related to other conditions unless specifically for those conditions.
It is not known if colchicine capsules are safe and effective in children.

Who should not take colchicine capsules?

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

What should I tell my healthcare provider before taking colchicine capsules?

Before you take colchicine capsules, tell your healthcare provider:

- about all of your medical conditions
- if you have kidney or liver problems
- if you are pregnant or plan to become pregnant. It is not known if colchicine capsules can harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- if you are breastfeeding or plan to breastfeed. Colchicine can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take colchicine capsules.
- if you are a male with a female partner who can become pregnant. Receiving treatment with colchicine capsules may be related to infertility in some men that is reversible when treatment

is stopped.

Tell your healthcare provider about all the medicines you take, including prescription, over-the-counter medicines, vitamins, or herbal supplements.

- Using colchicine capsules with certain other medicines can affect each other causing serious side effects and/or death.
- Do not take colchicine capsules with other medicines unless your healthcare provider tells you to.
- Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.
- Especially tell your healthcare provider if you take:
  - medicines that may affect how your liver works (CYP3A4 inhibitors)
  - cyclosporine (Neoral, Gengraf, Sandimmune)
  - cholesterol lowering medicines
  - antibiotics

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 affect colchicine capsules.

How should I take colchicine capsules?

- Take colchicine capsules exactly as your healthcare provider tells you to take it.
- Colchicine capsules can be taken with or without food.
- If you take too much colchicine capsules call your healthcare provider or go to the nearest hospital emergency room right away.
- Do not stop taking colchicine capsules unless your healthcare provider tells you to.
- If you miss a dose of colchicine capsules, take it as soon as you remember. If it is almost time for your next dose, 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 capsules, tell your healthcare provider.

What should I avoid while taking colchicine capsules?

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

What are the possible side effects of colchicine capsules?

Colchicine capsules can cause serious side effects or death. See **"What is the most important information I should know about colchicine capsules?"**

Get medical help right away, if you have:

- unusual bleeding or bruising
- increased infections
- weakness or fatigue
- muscle weakness or pain
- numbness or tingling in your fingers or toes
- pale or gray color to your lips, tongue, or palms of your hands
- severe diarrhea or vomiting

The most common side effects of colchicine capsules include 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 capsules. 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 capsules?

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

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

General information about the safe and effective use of colchicine capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take colchicine capsules for a condition for which it was not prescribed. Do not give colchicine capsules 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 capsules. If you would like more information, talk to your pharmacist or healthcare provider for information about colchicine capsules that is written for health professionals.

For more information, call 1-877-770-3183.

What are the ingredients in colchicine capsules?

Active Ingredient: Colchicine, USP

Inactive Ingredients: colloidal silicon dioxide, lactose anhydrous, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate. The capsule shell contains ammonium hydroxide, FD&C Blue #1, ferrosoferric oxide, gelatin, propylene glycol, shellac, titanium dioxide and yellow iron oxide.

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

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