# MEDICATION GUIDE

## COLCRYS
## (KOL-kris)

## (colchicine) tablets

Read the Medication Guide that comes with COLCRYS 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 COLCRYS when you start taking it and at regular checkups.

**What is the most important information I should know about COLCRYS?**
COLCRYS can cause serious side effects or death if levels of COLCRYS are too high in your body.

- Taking certain medicines with COLCRYS can cause your level of COLCRYS 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 COLCRYS may need to be changed.

- Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

- Even medicines that you take for a short period of time, such as antibiotics, can interact with COLCRYS 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 COLCRYS.

- 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 COLCRYS out of the reach of children.

**What is COLCRYS?**
COLCRYS is a prescription medicine used to:
- prevent and treat gout flares in adults
- treat familial Mediterranean fever (FMF) in adults and children age four or older

COLCRYS is 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 COLCRYS?**
Do not take COLCRYS 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 I should know about COLCRYS?"

**What should I tell my healthcare provider before starting COLCRYS?**
See "What is the most important information I should know about COLCRYS?"

Before you take COLCRYS 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 COLCRYS will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed. COLCRYS passes into your breast milk. You and your healthcare provider should decide if you will take COLCRYS or breast-feed. If you take COLCRYS and breast-feed, 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 I should know about COLCRYS?" Do not start a new medicine without talking to your healthcare provider.

Using COLCRYS 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 COLCRYS. Talk to your healthcare provider about whether the medications you are taking might interact with COLCRYS, and what side effects to look for.

**How should I take COLCRYS?**
- Take COLCRYS exactly as your healthcare provider tells you to take it. **If you are not sure about your dosing**, call your healthcare provider.
- COLCRYS can be taken with or without food.
- If you take too much COLCRYS go to the nearest hospital emergency room right away.
- Do not stop taking COLCRYS even if you start to feel better, unless your healthcare provider tells you.
- Your healthcare provider may do blood tests while you take COLCRYS.
- If you take COLCRYS 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 COLCRYS daily, report this to your healthcare provider.

**What should I avoid while taking COLCRYS?**
- Avoid eating grapefruit or drinking grapefruit juice while taking COLCRYS. It can increase your chances of getting serious side effects.

**What are the possible side effects of COLCRYS?**
COLCRYS can cause serious side effects or even cause death. See "What is the most important information I should know about COLCRYS?"

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 COLCRYS in people who have gout flares is diarrhea.

**FMF:** The most common side effects of COLCRYS 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 COLCRYS. 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 COLCRYS?**
- Store COLCRYS at room temperature between 68° and 77°F (20° to 25°C).
- Keep COLCRYS in a tightly closed container.
- Keep COLCRYS out of the light.

**Keep COLCRYS and all medicines out of the reach of children.**

**General Information about COLCRYS**
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use COLCRYS for a condition for which it was not prescribed. Do not give COLCRYS 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 COLCRYS. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about COLCRYS that is written for healthcare professionals.

For more information, go to www.COLCRYS.com or call 1-877-825-3327.

**What are the ingredients in COLCRYS?**
Active Ingredient: Colchicine

Inactive Ingredients: carnauba wax, FD&C blue #2, FD&C red #40, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, sodium starch glycolate, titanium dioxide, and triacetin.

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

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