

MEDICATION GUIDE

COLCRYS[®] (KOL-kris)

(colchicine, USP) 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 even death if COLCRYS levels are too high in your body. Keep COLCRYS out of the reach of children.

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.

Certain medicines when taken with COLCRYS can cause the levels of COLCRYS to be too high in your body. It is important for you to tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. COLCRYS and other medicines may affect each other causing serious side effects or even death. Do not start taking a new medicine without telling your healthcare provider or pharmacist.

Even medications that you might take for a short period of time, such as antibiotics, can interact with COLCRYS and cause serious side effects or death.

Especially tell your healthcare provider if you take:

- clarithromycin (Biaxin[®])
- telithromycin (Ketek[®])
- cyclosporine (Neoral[®], Gengraf[®], Sandimmune[®])
- ketoconazole (Nizoral[®])
- itraconazole (Sporanox[®])
- HIV protease inhibitors
- nefazodone (Serzone[®])

This is not a complete list of all the medicines that can interact with COLCRYS. Talk to your healthcare provider or pharmacist to find out if taking COLCRYS with the other medicines you are taking could be dangerous.

Talk to your healthcare provider before taking any new medicine.

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.

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.

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

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.
 - Your healthcare provider might tell you to take extra COLCRYS. You will be told to take 2 extra tablets then 1 extra tablet an hour later, and if you forget to take the extra tablet, take it when you remember, don't take any more COLCRYS for at least 12 hours, then continue your normal dose schedule.

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

Prophylaxis and Treatment of Gout Flares: The most common side effect of COLCRYS is diarrhea.

FMF: The most common side effects of COLCRYS 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 1-888-351-3786.

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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U.S. Patent Nos. 7,601,758; 7,619,004 and other patents pending

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