Medication Guide
Cordarone® 'KOR-DU-RŌN Tablets
(amiodarone HCl)

Rx only

Read the Medication Guide that comes with Cordarone Tablets before you start taking them and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Cordarone Tablets?
Cordarone Tablets can cause serious side effects that can lead to death including:

- **lung damage**
- **liver damage**
- **worse heartbeat problems**
- **thyroid problems**

Call your doctor or get medical help right away if you have any symptoms such as the following:

- shortness of breath, wheezing, or any other trouble breathing; coughing, chest pain, or spitting up of blood
- nausea or vomiting; passing brown or dark-colored urine; feel more tired than usual; your skin and whites of your eyes get yellow; or have stomach pain
- heart pounding, skipping a beat, beating very fast or very slowly; feel light-headed or faint
- weakness, weight loss or weight gain, heat or cold intolerance, hair thinning, sweating, changes in your menses, swelling of your neck (goiter), nervousness, irritability, restlessness, decreased concentration, depression in the elderly, or tremor.

Because of these possible side effects, Cordarone Tablets should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias, for which other treatments did not work or were not tolerated.

Cordarone Tablets can cause other serious side effects. See **"What are the possible or reasonably likely side effects of Cordarone Tablets?"** for more information.

If you get serious side effects during treatment with Cordarone Tablets you may need to stop Cordarone Tablets, have your dose changed, or get medical treatment. Talk with your doctor before you stop taking Cordarone Tablets.

You may still have side effects after stopping Cordarone Tablets because the medicine stays in your body months after treatment is stopped.

Tell all your healthcare providers that you take or took Cordarone Tablets. This information is very important for other medical treatments or surgeries you may have.

What are Cordarone Tablets?
Cordarone is a medicine used in adults to treat life-threatening heartbeat problems called ventricular arrhythmias, for which other treatment did not work or was not tolerated. Cordarone Tablets have not been shown to help people with life-threatening heartbeat problems live longer. Treatment with Cordarone Tablets should be started in a hospital to monitor your condition. You should have regular check-ups, blood tests, chest x-rays, and eye exams before and during treatment with Cordarone Tablets to check for serious side effects.

Cordarone Tablets have not been studied in children.

Who should not take Cordarone Tablets?
Do not take Cordarone Tablets if you:

- **have certain heart conditions** (heart block, very slow heart rate, or slow heart rate with dizziness or lightheadedness)
- **have an allergy to amiodarone, iodine, or any of the other ingredients in Cordarone Tablets.** See the end of this Medication Guide for a complete list of ingredients in Cordarone Tablets.

What should I tell my doctor before starting Cordarone Tablets?
Tell your doctor about all of your medical conditions including if you:

- **have lung or breathing problems**
- **have liver problems**
- **have or had thyroid problems**
- **have blood pressure problems**
- **are pregnant or planning to become pregnant.** Cordarone can harm your unborn baby. Cordarone can stay in your body for months after treatment is stopped. Therefore, talk with your doctor before you plan to get pregnant.
- **are breastfeeding.** Cordarone passes into your milk and can harm your baby. You should not breast feed while taking Cordarone. Also, Cordarone can stay in your body for months after treatment is stopped.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Cordarone Tablets and certain other medicines can interact with each other causing serious side effects. Sometimes the dose of Cordarone Tablets or other medicines must be changed when they are used together. Especially, tell your doctor if you are taking:

- antibiotic medicines used to treat infections
- depression medicines
- blood thinner medicines
- HIV or AIDS medicines
- cimetidine (Tagamet®), a medicine for stomach ulcers or indigestion
- loratadine (for example: Claritin®, Alavert®), a medicine for allergy symptoms
- seizure medicines
- diabetes medicines
- cyclosporine, an immunosuppressive medicine
- dextromethorphan, a cough medicine
- medicines for your heart, circulation, or blood pressure
- water pills (diuretics)
- high cholesterol or bile medicines
- narcotic pain medicines
- St. John's Wort

Know the medicines you take. Keep a list of them with you at all times and show it to your doctor and pharmacist each time you get a new medicine. Do not take any new medicines while you are taking Cordarone Tablets unless you have talked with your doctor.

How should I take Cordarone Tablets?

- **Take Cordarone Tablets exactly as prescribed by your doctor.**
- The dose of Cordarone Tablets you take has been specially chosen for you by your doctor and may change during treatment. Keep taking your medicine until your doctor tells you to stop. Do not stop taking it because you feel better. Your condition may get worse. Talk with your doctor if you have side effects.
- Your doctor will tell you to take your dose of Cordarone Tablets with or without meals. Make sure you take Cordarone Tablets the same way each time.
- **Do not drink grapefruit juice during treatment with Cordarone Tablets.** Grapefruit juice affects how Cordarone is absorbed in the stomach.

- Taking too many Cordarone Tablets can be dangerous. If you take too many Cordarone Tablets, call your doctor or go to the nearest hospital right away. You may need medical care right away.

- If you miss a dose, do not take a double dose to make up for the dose you missed. Continue with your next regularly scheduled dose.

What should I avoid while taking Cordarone Tablets?

- **Do not drink grapefruit juice during treatment with Cordarone Tablets.** Grapefruit juice affects how Cordarone is absorbed in the stomach.

- **Avoid exposing your skin to the sun or sun lamps.** Cordarone Tablets can cause a photosensitive reaction. Wear sun-block cream or protective clothing when out in the sun.

- **Avoid pregnancy during treatment with Cordarone Tablets.** Cordarone can harm your unborn baby.

- **Do not breastfeed while taking Cordarone Tablets.** Cordarone passes into your milk and can harm your baby.

What are the possible or reasonably likely side effects of Cordarone Tablets?
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Cordarone Tablets can cause serious side effects that lead to death including lung damage, liver damage, worse heartbeat problems, and thyroid problems. See **"What is the most important information I should know about Cordarone Tablets?"**

Some other serious side effects of Cordarone Tablets include:

- **vision problems that may lead to permanent blindness.** You should have regular eye exams before and during treatment with Cordarone Tablets. Call your doctor if you have blurred vision, see halos, or your eyes become sensitive to light.

- **nerve problems.** Cordarone Tablets can cause a feeling of "pins and needles" or numbness in the hands, legs, or feet, muscle weakness, uncontrolled movements, poor coordination, and trouble walking.

- **thyroid problems.** Cordarone Tablets can cause thyroid problems, including low thyroid function or overactive thyroid function. Your doctor may arrange regular blood tests to check your thyroid function during treatment with Cordarone. Call your doctor if you have weakness, weight loss or weight gain, heat or cold intolerance, hair thinning, sweating, changes in your menses, swelling of your neck (goiter), nervousness, irritability, restlessness, decreased concentration, depression in the elderly, or tremor.

- **skin problems.** Cordarone Tablets can cause your skin to be more sensitive to the sun or to turn a bluish-gray color. In most patients, skin color slowly returns to normal after stopping Cordarone Tablets. In some patients, skin color does not return to normal.

Other side effects of Cordarone Tablets include nausea, vomiting, constipation, and loss of appetite.

Call your doctor about any side effect that bothers you.

These are not all the side effects with Cordarone Tablets. For more information, ask your doctor or pharmacist.

How should I store Cordarone Tablets?

- Store Cordarone Tablets at room temperature. Protect from light. Keep Cordarone Tablets in a tightly closed container.
- Safely dispose of Cordarone Tablets that are out-of-date or no longer needed.
- **Keep Cordarone Tablets and all medicines out of the reach of children.**

General information about Cordarone Tablets
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Cordarone Tablets for a condition for which it was not prescribed. Do not share Cordarone with other people, even if they have the same symptoms that you have. It may harm them.

If you have any questions or concerns about Cordarone Tablets, ask your doctor or healthcare provider. This Medication Guide summarizes the most important information about Cordarone Tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Cordarone Tablets that was written for healthcare professionals.

This Medication Guide may have been revised after this copy was produced. For more information and the most current Medication Guide, please visit www.wyeth.com or call our medical communications department toll-free at 1-800-934-5556.

What are the ingredients in Cordarone Tablets?
Active Ingredient: amiodarone HCl

Inactive Ingredients: colloidal silicon dioxide, lactose, magnesium stearate, povidone, starch, and FD&C Red 40.

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

Rx only

Manufactured for

Wyeth®

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