



Patient Information Sheet

Amiodarone hydrochloride (marketed as Cordarone)

This is a summary of the most important information about amiodarone. For details, talk to your healthcare professional.

FDA ALERT [05/2005] – Lung and Liver Damage and Worsening Heart Problems. Amiodarone should only be used to treat adults with life threatening irregular heartbeats, called ventricular arrhythmias, when other treatments have not worked or have not been tolerated. Amiodarone may cause serious side effects, including lung damage, liver damage, and worsened irregular heartbeat. These can lead to death. Call your healthcare professional or get medical help right away if you feel:

- **Shortness of breath; wheezing; or any trouble breathing;**
- **Cough; chest pain; or spitting up blood**
- **Nausea or vomiting; passing dark-colored urine; unusually tired; have yellow skin; or stomach pain**
- **Changes in your heart beat, such as a pounding heart; very rapid or very slow heart beat**
- **Faintness or light-headedness**

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Is Amiodarone?

Amiodarone is a medicine used to treat adults with life-threatening irregular heartbeats, called ventricular arrhythmias. Because of its serious side effects, it is used only when other treatments have not worked or are not tolerated.

Who Should Not Take Amiodarone?

Do not take amiodarone if you have:

- A serious condition called heart block that can make your heart beat too slow
- Very slow heart rate
- Slow heart rate with dizziness or light-headedness

What Are The Risks?

- Lung and Liver Damage and Worsening Heart Problems: See FDA Alert above.

You may have other side effects while taking amiodarone. Amiodarone stays in your body for months, so these side effects may continue after treatment is stopped.

- **Serious vision problems:** Tell your healthcare professional if your vision blurs, you see halos, or your eyes become light sensitive.
- **Muscle problems:** You may have numbness or “pins and needles” in your arms or legs, muscle weakness, uncontrolled movements, poor coordination, and difficulty walking.

- **Thyroid problems:** Tell your healthcare professional if you have weight loss or gain, restlessness, body weakness, become over sensitive to heat or cold, hair thinning, sweating, menstrual changes, or neck swelling (goiter).
- **Skin problems:** Your skin may change to a blue-gray color or you may have increased sensitivity to the sun. Avoid exposure to the sun or sun lamps. Use sunblock or protective clothing when out in the sun.
- **Digestion changes:** You may have nausea, vomiting, constipation, and loss of appetite.
- **Pregnancy:** Amiodarone can harm your unborn baby. You should not plan to become pregnant while taking amiodarone and for some time after you stop taking amiodarone.
- **Breast-feeding:** Amiodarone passes into your milk and can harm your baby. You should not breast-feed while taking amiodarone and for some time after you stop taking amiodarone.

Are There Any Interactions With Drugs Or Foods?

Amiodarone may interact with other medicines, causing serious side effects. Tell your healthcare professional about the other medicines you take or plan to take, especially:

- Antibiotics called fluoroquinolones, azoles, and macrolide antibiotics
- Digoxin (also called Lanoxin, a drug used to treat irregular heartbeat or heart failure)
- Other drugs to control heartbeat, such as quinidine, procainamide (also called Procan or Procanbid), disopyramide (also called Norpace), and phenytoin (also called Dilantin).
- Warfarin (a drug used to treat blood clots)
- Simvastatin (also called Zocor, a drug used to treat high cholesterol)
- Drugs to treat high blood pressure, called beta blockers and calcium channel blockers

Do not drink grapefruit juice while you are being treated with amiodarone because it affects how the stomach absorbs amiodarone. Drinking grapefruit juice while taking amiodarone may cause an overdose.

How Do I Take Amiodarone?

- Treatment should be started in a hospital so that your condition can be monitored.
- Your healthcare professional will tell you to take amiodarone with or without meals. Take amiodarone tablets the same way each time.
- If you miss a dose, do not take a double dose to make up for the missed dose. Continue with your next scheduled dose.

**Cordarone FDA Approved 1985
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