

PART III: CONSUMER INFORMATION

**Pr AMIODARONE
(Amiodarone Hydrochloride Tablets)
200 mg**

This leaflet is part III of a three-part “Product Monograph” published when AMIODARONE (Amiodarone Hydrochloride Tablets) was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about AMIODARONE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- Treatment of certain abnormal heart rhythms (arrhythmias).

What it does:

- AMIODARONE has been prescribed to you by your doctor to restore or maintain a normal heart rhythm.

When it should not be used:

- Do not use AMIODARONE if you are allergic to it or to any of the components of its formulation (see full list of components below). Contact your doctor **immediately** if you experience an allergic reaction or any severe or unusual side effects.
- Do not use AMIODARONE if you have hepatitis, thyroid problems, or pulmonary disease (certain lung problems).

What the medicinal ingredient is:

AMIODARONE is available in tablets containing 200 mg amiodarone hydrochloride as the active ingredient.

What the nonmedicinal ingredients are:

The non-medicinal ingredients in AMIODARONE are: colloidal silicone dioxide, croscarmellose sodium, FD&C red #40 aluminum lake (contains aluminum hydroxide and red 40 dye), lactose monohydrate, magnesium stearate, polysorbate 80, povidone, pregelatinized starch and talc.

What dosage forms it comes in:

AMIODARONE (Amiodarone Hydrochloride Tablets) 200 mg is available as an oral tablet.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- AMIODARONE is intended for use only in patients with the indicated life-threatening arrhythmias because its use is accompanied by substantial toxicity.
- Pulmonary fibrosis (permanent scarring of the lungs) can occur and can be fatal.
- Like other antiarrhythmics, AMIODARONE can worsen or start an irregular heartbeat (arrhythmias).
- Liver injury is common with amiodarone hydrochloride, but is usually mild, however it can be serious **and even fatal** in some cases.

BEFORE you use AMIODARONE talk to your doctor if:

- you have hepatitis, thyroid problems or lung abnormalities,
- you are breast feeding, pregnant or planning on becoming pregnant,
- you anticipate undergoing any surgery,
- you have any allergies to this drug or its ingredients or components of the container,
- you are taking any medications (see **INTERACTIONS WITH THIS MEDICATION**).

Precautions when taking AMIODARONE

Consult your doctor if you experience these or other side effects, as the dose may have to be adjusted:

- AMIODARONE may cause a worsening of the existing arrhythmias or precipitate a new arrhythmia.
- Both hyper - and hypothyroidism (too much or too little thyroid hormone released into the blood by the thyroid gland) may occur during, or soon after treatment with AMIODARONE.
- One of the most serious complications is pulmonary (lung) toxicity, characterized by scarring or inflammation of the lungs. Clinical symptoms include cough, progressive shortness of breath, accompanied by weight loss and weakness.
- Amiodarone hydrochloride induces photosensitization in about 10% of patients. Sunscreen preparations or protective clothing may afford some protection to individual patients experiencing photosensitization. Blue-grey discoloration of exposed skin has been reported during long-term treatment. With discontinuation of therapy, the pigmentation fades slowly over a period of up to several years. The risk may be increased in patients of fair complexion or those with excessive sun exposure, and may be related to cumulative dose and duration of therapy.
- Loss of vision or other visual disturbances such as visual halos or blurred vision.
- Symptoms of nerve damage (peripheral neuropathy) such as pain, burning, or numbness.
- Progressive skin rash, often with blisters or lesions, which may lead to severe skin reactions that are sometimes fatal.

INTERACTIONS WITH THIS MEDICATION

You should ensure that your doctor and pharmacist know all the medicines you are taking, prescription, non-prescription or herbal.

Drugs that may interact with AMIODARONE include:

Azoles, Cholestyramine,
Beta blockers (e.g., propranolol),
Calcium channel antagonists (e.g., verapamil),
Cholesterol-lowering medications (e.g., simvastatin, atorvastatin),
Cimetidine, Cyclosporine,
Dabigatran Digitalis,
Digoxin, Disopyramide,
Fentanyl, Flecainide,
Fluoroquinolones, Lidocaine,
Macrolide Antibiotics, Phenytoin
Procainamide, Protease inhibitors (e.g., indinavir)
Quinidine,
Sofosbuvir (alone or in combination with other antiviral drugs to treat Hepatitis C such as daclatasvir, simeprevir, ledipasvir)
Warfarin

Grapefruit Juice and the herbal preparation St. John’s Wort may also interact with AMIODARONE.

PROPER USE OF THIS MEDICATION

Usual Adult Dose:

- It is very important that you take AMIODARONE exactly as your doctor has instructed.
- Never increase or decrease the amount of AMIODARONE you are taking unless your doctor tells you to.
- Loading Dose: normally 800 to 1600 mg/day for 1 to 3 weeks (occasionally longer). Maintenance Dose: normally 600 to 800 mg/day for one month and then 200 to 400 mg/day (occasionally 600 mg/day).
- AMIODARONE may be taken as a single daily dose, or in patients with severe gastrointestinal intolerance, as a twice a day dose.

Overdose:

What to do in case of overdose

Contact a health care practitioner, the nearest hospital emergency department or the regional Poison Control Centre immediately, even though you may not feel sick.

Missed Dose:

If you happen to miss a dose, do not try to make up for it by doubling up on the dose next time. Just take your next regularly scheduled dose and try not to miss any more.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

- You may experience side effects with the use of AMIODARONE.

North American experience with chronic oral amiodarone hydrochloride therapy suggest that amiodarone-associated adverse drug reactions are very common, having occurred in approximately 75% of patients taking 400 mg or more per day. The most serious adverse effects associated with the use of amiodarone hydrochloride involve your lungs, irregularities of your heart beat and hepatitis. Symptoms that suggest side effects relating to lung inflammation or scarring include: progressive shortness of breath, cough, weakness and weight loss. Symptoms that may suggest an irregularity of heart beat include: fainting, dizziness, light-headedness, weakness and chest pain.

Your doctor should monitor your blood for liver function. The following symptoms may be signs of liver problems: prolonged nausea and vomiting, abdominal pain or discolouration of the skin.

Other symptoms causing discontinuations less often have included disturbances of vision, reactions of the skin to sunlight, blue skin discoloration, life-threatening or even fatal skin reactions, eczema, hyperthyroidism and hypothyroidism.

Hypotension (low blood pressure), while seen, is uncommon (less than 1%) during amiodarone hydrochloride tablets therapy.

Chronic (i.e., long-term) administration of amiodarone hydrochloride Tablets in rare instances may lead to the development of nerve damage (peripheral neuropathy) that may resolve when AMIODARONE is discontinued, but this resolution has been slow and incomplete (see Precautions when taking AMIODARONE).

Should you experience any of these while taking AMIODARONE, consult your doctor immediately.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist In all cases	Stop taking drug and call your doctor or pharmacist
Tremor/abnormal involuntary movements, lack of coordination, abnormal gait, dizziness		✓
Blue skin discoloration		✓
Severe skin reactions (e.g. progressive skin rash with blisters) or allergic reaction (e.g. swelling of the lips, face, tongue and throat, trouble breathing)		✓
Low blood pressure (fainting episodes, severe dizziness)		✓
Shortness of breath, chest pain, irregular heart beat, racing heart	✓	
Bleeding abnormalities (excessive bruising, easy bleeding (e.g., when brushing teeth))	✓	
Visual disturbances (halos or blurred vision),	✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist In all cases	Stop taking drug and call your doctor or pharmacist
visual impairment		
Vomiting, abdominal pain, diarrhea	✓	
Solar dermatitis/ photosensitivity (skin becomes sensitive to light)	✓	
Paresthesias (sensation of tingling, burning, crawling of the skin) and Peripheral motor and sensory neuropathies (e.g., muscular weakness)	✓	
Cognitive disturbances (e.g., confusion, inability to concentrate)	✓	
Liver problems (e.g., yellowing skin or eyes, abdominal pain or vomiting)	✓	
Alopecia (loss of hair)	✓	

This is not a complete list of side effects. For any unexpected effects while taking AMIODARONE, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep bottle tightly closed.
- Store at 15° to 30°C.
- Protect from light.
- Keep out of reach of children.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

REMINDER: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found by contacting Sanis Health Inc. at:
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