IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PRO-AMIODARONE - 200
Amiodarone Tablets BP
200 mg amiodarone hydrochloride

IMPORTANT: PLEASE READ

This leaflet is part III of a three-part "Product Monograph" published when PRO-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 PRO-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:

- **PRO-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 **PRO-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 **PRO-AMIODARONE** if you have hepatitis, thyroid problems, or pulmonary disease (certain lung problems).

What the medicinal ingredient is:

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

What the nonmedicinal ingredients are:

The non-medicinal ingredients in **PRO-AMIODARONE** are: colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C Red # 40 Aluminum Lake 38 to 42% and magnesium stearate.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- PRO-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, PRO-AMIODARONE can worsen or start an irregular heartbeat (arrhythmias).
- Liver injury is common with PRO-AMIODARONE, but is usually mild, however it can be serious **and even fatal** in some cases.

BEFORE you use PRO-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 PRO-AMIODARONE

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

- PRO-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 PRO-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.
- PRO-AMIODARONE 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 PRO-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 PRO-AMIODARONE.

PROPER USE OF THIS MEDICATION

Usual Adult Dose:

- It is very important that you take **PRO-AMIODARONE** exactly as your doctor has instructed.
- Never increase or decrease the amount of **PRO-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).
- **PRO-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 PRO-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 Tablets therapy.

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

Should you experience any of these while taking PRO-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 discolouration		✓
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), 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 PRO-AMIODARONE, contact your doctor or pharmacist.

HOW TO STORE IT

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

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- **Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or**
- **Calling toll-free at 1-866-234-2345.**

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

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

This leaflet was prepared by
Pro Doc Ltée, Laval, Québec, H7L 3W9

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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.