

## MAYNE PHARMA LAUNCHES AMIODARONE TABLETS 200MG IN THE UNITED STATES

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Apr. 16, 2018, Greenville, N.C.: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of amiodarone tablets, 200mg, in the United States. Amiodarone is a generic alternative to Cordarone® tablets, indicated for life-threatening recurrent ventricular arrhythmia. This launch complements the existing amiodarone product range that includes 100mg and 400mg dose strengths.

Mayne Pharma's CEO Scott Richards said, "Amiodarone tablets is one of the first products to be manufactured at our new Greenville, North Carolina, manufacturing facility which recently was completed. This new solid oral-dose manufacturing facility quadruples the company's U.S. manufacturing capacity to well over 1 billion doses annually, and importantly introduces significant capacity to manufacture potent compounds and new capability to manufacture modified-release bead/pellet products."

Mayne Pharma directly markets more than 55 products and has a growing pipeline of more than 30 generic and branded drug products targeting U.S. markets with IQVIA sales greater than \$5 billion. According to IQVIA, U.S. brand and generic sales of amiodarone tablets, 200mg, were approximately \$22 million for the 12 months ending Jan. 31, 2018.

### Important Safety Information

**Amiodarone is intended for use only in patients with the indicated life-threatening arrhythmias because its use is accompanied by substantial toxicity.**

**Amiodarone has several potentially fatal toxicities, the most important of which is pulmonary toxicity (hypersensitivity pneumonitis or interstitial/alveolar pneumonitis) that has resulted in clinically manifest disease at rates as high as 10 to 17% in some series of patients with ventricular arrhythmias given doses around 400 mg/day, and as abnormal diffusion capacity without symptoms in a much higher percentage of patients. Pulmonary toxicity has been fatal about 10% of the time. Liver injury is common with amiodarone, but is usually mild and evidenced only by abnormal liver enzymes. Overt liver disease can occur, however, and has been fatal in a few cases. Like other antiarrhythmics, amiodarone can exacerbate the arrhythmia, e.g., by making the arrhythmia less well tolerated or more difficult to reverse. This has occurred in 2 to 5% of patients in various series, and significant heart block or sinus bradycardia has been seen in 2 to 5%. All of these events should be manageable in the proper clinical setting in most cases. Although the frequency of such proarrhythmic events does not appear greater with amiodarone than with many other agents used in this population, the effects are prolonged when they occur.**

**Even in patients at high risk of arrhythmic death, in whom the toxicity of amiodarone is an acceptable risk, amiodarone poses major management problems that could be life-threatening in a population at risk of sudden death, so that every effort should be made to utilize alternative agents first.**

**The difficulty of using amiodarone effectively and safely itself poses a significant risk to patients. Patients with the indicated arrhythmias must be hospitalized while the loading dose of amiodarone is given, and a response generally requires at least one week, usually**

**two or more. Because absorption and elimination are variable, maintenance-dose selection is difficult, and it is not unusual to require dosage decrease or discontinuation of treatment. In a retrospective survey of 192 patients with ventricular tachyarrhythmias, 84 required dose reduction and 18 required at least temporary discontinuation because of adverse effects, and several series have reported 15 to 20% overall frequencies of discontinuation due to adverse reactions. The time at which a previously controlled life-threatening arrhythmia will recur after discontinuation or dose adjustment is unpredictable, ranging from weeks to months. The patient is obviously at great risk during this time and may need prolonged hospitalization. Attempts to substitute other antiarrhythmic agents when amiodarone must be stopped will be made difficult by the gradually, but unpredictably, changing amiodarone body burden. A similar problem exists when amiodarone is not effective; it still poses the risk of an interaction with whatever subsequent treatment is tried.**

*Amiodarone is contraindicated in patients with cardiogenic shock; severe sinus-node dysfunction, causing marked sinus bradycardia; second or third-degree atrioventricular block; and when episodes of bradycardia have caused syncope (except when used in conjunction with a pacemaker).*

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### Indication and Usage

*Because of its life-threatening side effects and the substantial management difficulties associated with its use, amiodarone is indicated only for the treatment of the following documented, life-threatening recurrent ventricular arrhythmias when these have not responded to adequate doses of other available antiarrhythmics or when alternative agents could not be tolerated.*

1. *Recurrent ventricular fibrillation.*
2. *Recurrent hemodynamically unstable ventricular tachycardia.*

*As is the case for other antiarrhythmic agents, there is no evidence from controlled trials that the use of amiodarone hydrochloride tablets favorably affects survival.*

*Amiodarone should be used only by physicians familiar with and with access to (directly or through referral) the use of all available modalities for treating recurrent life-threatening ventricular arrhythmias, and who have access to appropriate monitoring facilities, including in-hospital and ambulatory continuous electrocardiographic monitoring and electrophysiologic techniques. Because of the life-threatening nature of the arrhythmias treated, potential interactions with prior therapy, and potential exacerbation of the arrhythmia, initiation of therapy with amiodarone should be carried out in the hospital.*





## News Release

To report a suspected adverse reaction from one of our products, please contact Mayne Pharma at 1.844.825.8500 or [maynepharmamc@dlss.com](mailto:maynepharmamc@dlss.com), or FDA at 1.800.FDA.1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### For further information contact:

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### About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialize branded and generic pharmaceuticals, providing patients with access to better and more affordable medicines. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialized in numerous products that have been marketed around the world.

Mayne Pharma has two product development and manufacturing facilities based in Salisbury, Australia, and Greenville, N.C., USA, with expertise in the formulation of complex oral dose forms including potent compounds, controlled substances, modified-release products and inherently unstable compounds.

Cordarone® is a registered trademark of Sanofi.

