For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information
CORDARONE®

AMIODARONE TABLETS IP

COMPOSITION
Cordarone X : Each tablet contains 200mg of Amiodarone HCl IP ;
Cordarone : Each tablet contains 100mg of Amiodarone HCl IP

THERAPEUTIC INDICATIONS
Severe rhythm disorders not responding to other therapies or when other treatments cannot be used; tachyarrhythmias associated with WPW Syndrome, atrial flutter and fibrillation when other drugs cannot be used, all types of tachyarrhythmias of paroxysmal nature including supraventricular, nodal and ventricular tachycardias, ventricular fibrillation, when other drugs cannot be used.

DOSAGE & ADMINISTRATION
Initial stabilization : 200mg tid, continued for 1 week. Dosage then reduced to 200mg bid for 1 week.
Maintenance : 200mg daily, or less.

SAFETY-RELATED INFORMATION
Contraindications: Sinus bradycardia, sino-atrial heart blocks and risk of sick sinus syndrome, severe atrioventricular conduction disorders unless fitted with a pacemaker. Combination with drugs which may induce torsades de pointes, thyroid dysfunction, known hypersensitivity to iodine or amiodarone or any excipients, pregnancy; lactation.
Warnings: Cardiac disorders – ECG changes such as QT prolongation with the possible development of U-waves, hyperthyroidism may occur during treatment or upto several months after discontinuation. Severe cases with clinical presentation of thyrotoxicosis, sometimes fatal require emergency therapeutic management. Amiodarone may induce peripheral sensorimotor neuropathy and / or myopathy. If blurred or decreased vision, complete ophthalmologic examination including fundoscopy should be promptly performed. Onset of new arrhythmias or worsening of treated arrhythmias sometimes fatal have been reported. Cases of severe, potentially life-threatening bradycardia and heart block have been observed when amiodarone is used in combination with sofosbuvir in combination with another hepatitis C virus (HCV) direct acting antiviral (DAA). Therefore, coadministration of these agents with amiodarone is not recommended. In retrospective studies, amiodarone use in the transplant recipient prior to heart transplant has been associated with an increased risk of primary graft dysfunction. For persons who are on the heart transplant waiting list, consideration should be given to use an alternative antiarrhythmic drug as early as possible. Onset of dyspnoea or non-productive cough may be related to pulmonary toxicity such as interstitial pneumonitis. Very rare cases of severe respiratory complications have been observed usually in the period immediately following surgery. Close monitoring of liver function tests (transaminases) is recommended. Clinical or biological signs of chronic liver disorders due to oral amiodarone may be minimal and reversible after treatment withdrawal. Concomitant use with beta blockers, calcium channel inhibitors, stimulating laxatives is not recommended. If symptoms or signs of SJS, TEN (e.g. progressive skin rash often with blisters or mucosal lesions) are present amiodarone treatment should be discontinued immediately.
Precautions: Minimum effective dose should be given. Avoid exposure to sun and to use protective measures during therapy. Monitoring of ECG and serum potassium is recommended before starting amiodarone. Monitoring transaminases and ECG is recommended during treatment. Clinical and biological usTSH monitoring is recommended. Amiodarone may interfere with radio-iodine uptake. Safety and efficacy has not been established in paediatric patients. Before surgery, anaesthetist needs to be informed that patient is taking amiodarone.
Pregnancy & lactation: Contraindicated during pregnancy and lactation.
Adverse reactions: Very common : Corneal microdeposits, may be associated with coloured halos in dazzling light or blurred vision, benign gastrointestinal disorders, isolated increase in serum transaminases, photosensitivity. Common : Bradycardia, hypothyroidism, hyperthyroidism sometimes fatal; acute liver disorders and / or jaundice including hepatic failure; extrapyramidal tremor, nightmares, sleep disorders; pulmonary toxicity, slate grey or bluish pigmentation of the skin in case of prolonged treatment with high daily dosages.

For full prescribing information, please contact: **Sanofi Healthcare India Pvt Ltd.**. ***Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072***

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