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

Abridged Prescribing Information

**CORDARONE INJECTION**
**Amiodarone Intravenous Infusion IP**
**150mg/3ml**

**COMPOSITION**
Amiodarone HCl IP 150mg/3ml solution for IV injection in ampoules.
**THERAPEUTIC INDICATIONS**
Serious rhythm disorders, when oral route not appropriate: atrial rhythm disorders with rapid ventricular rhythm; WPW syndrome tachycardia; documented symptomatic, incapacitating ventricular rhythm disorders; cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock.
**DOSAGE AND ADMINISTRATION**
***Intravenous Infusion:*** 5mg/kg in 250ml of 5% dextrose solution administered over a period of 20-120 minutes, repeated 2 to 3 times per 24 hour period. *Maintenance treatment:* 10 to 20mg/kg/24 hours in 250ml of 5% dextrose over several days. The relay to oral administration should be started as soon as the first day of infusion.
***Intravenous Injection:*** 5mg/kg to be injected over 3 minutes. In case of cardiopulmonary resuscitation of shock resistant ventricular fibrillation, 1st dose of 300mg diluted in 20ml of 5% dextrose solution is administered via bolus IV injection. Additional 150mg IV dose may be considered if ventricular fibrillation persists.
**SAFETY RELATED INFORMATION**
**Contraindications:** Sinus bradycardia, sino-atrial blocks, 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 excipient; pregnancy unless exceptional circumstances ; lactation; bi or tri-fascicular conduction disorders unless a permanent pacemaker is fitted or patient is in special care unit and amiodarone is used under cover of electrosystolic pacing, severe arterial hypotension, circulatory collapse, hypotension, severe respiratory failure, myocardiopathy or heart failure. Contraindications do not apply when amiodarone is used in the emergency treatment of cardiopulmonary resuscitation of shock (defibrillator) resistant ventricular fibrillation.
**Pregnancy & Lactation:** amiodarone is contraindicated.**Warnings:** IV injection generally not advised because of haemodynamic risks, iv infusion is preferable whenever possible, IV injection only in case of emergency, to be done in ICU under continuous monitoring (ECG, blood pressure). Dosage is approximately 5mg/kg body weight. Except for cardio pulmonary resuscitation of shock resistant ventricular fibrillation, amiodarone should be injected over a minimum period of 3 minutes. IV injection should not be repeated less than 15 minutes following the first injection even if the latter was only 1 ampoule. Do not mix other preparations in the same syringe. Cardiac disorders (new arrhythmia or worsening) 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 recommendedIn 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. If blurred or decreased vision, complete ophthalmologic examination including fundoscopy should be promptly performed. 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. Concomitant use with beta blockers, calcium channel inhibitors, stimulating laxatives is not recommended.

**Precautions:** IV amiodarone should only be used in a special care unit under continuous monitoring (ECG, blood pressure). To avoid injection site reactions amiodarone IV should be administered through a central venous line. Caution in case of hypotension, severe respiratory failure, uncompensated or severe heart failure. Safety and efficacy not established in paediatric patients. Contains benzyl alcohol (reports of gasping syndrome in neonates). Anesthetist to be informed before surgery.
**Adverse reactions**: Common: Moderate bradycardia; injection site reactions such as pain, erythema, oedema, necrosis, extravasation, infiltration, inflammation, induration, thrombophlebitis, phlebitis, cellulitis, infection, pigmentation changes; decrease in blood pressure usually moderate and transient; severe hypotension or collapse following overdosage or a too rapid injection.

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

**Updated: January 2019**
**Source: CCDS Version 21 Dated 21 Dec 2018**