PACKAGE INSERT – Cordarone X Intravenous – Injection ampoule

NAME OF THE MEDICINE

Amiodarone hydrochloride

DOSAGE FORM

Solution for intravenous administration

METHOD OF PREPARATION

Preparation:

The standard recommended dose is 5 mg/kg body weight given by intravenous infusion over a period of 20 minutes to 2 hours. This should be administered as a dilute solution in 250 mL 5% glucose.

Ampoules in which a precipitate or cloudiness have formed should be discarded.

Compatibility:

CORDARONE X INTRAVENOUS INJECTION IS INCOMPATIBLE WITH SALINE AND SHOULD BE ADMINISTERED SOLELY IN 5% GLUCOSE SOLUTION.

Do not mix amiodarone with other preparations in the same syringe or infusion solution.

It has been shown that there is a physical incompatibility of heparin and aminophylline with amiodarone when mixed in an infusion administration set. It is recommended that amiodarone for infusion not be mixed with other drugs.

Experience has shown that amiodarone can be absorbed into PVC infusion bags and administration sets possibly because of the presence of plasticisers in PVC plastic. It is important to prepare the infusion solution immediately prior to use in either glass or rigid PVC bottles containing no plasticisers and use within 12 hours.

The use of medical equipment or devices containing plasticiser such as DEHP (di-2-ethylhexyl phthalate) in the presence of amiodarone injection may result in leaching out of DEHP. In order to minimise patient exposure to DEHP, the final amiodarone dilution for infusion may preferably be administered through non-DEHP containing sets.

IN-USE STORAGE CONDITIONS

Cordarone X Intravenous does not contain any preservative and should be prepared immediately prior to use and used within 12 hours.

SPONSOR

sanofi-aventis australia pty ltd
International Tower 3, Level 23
300 Barangaroo Avenue
Sydney NSW 2000
Freecall: 1800 818 806
Email: medinfo.australia@sanofi.com

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