2100 mg were associated with an increased risk of hypotension. Do not exceed an initial infusion rate of 30 mg/min.

Based on the experience from clinical studies of intravenous amiodarone, a maintenance infusion of up to 0.5 mg/min can be administered. Patients receiving intravenous amiodarone for longer than 3 weeks experienced a decrease in systolic blood pressure and an increase in the incidence of hypotension. Patients receiving intravenous amiodarone for up to 1 week had a 1% incidence of hypotension, 5% for at least 2 weeks, and 2% for at least 3 weeks. If the treatment is continued, carefully monitor these patients for adverse effects, especially for conduction disturbances.

**Initial Load:**

- **150 mg per 100 mL (in D5W)**

**DRUG INTERACTIONS**

**6.1**

1. **Hypotension**

   Hypotension (sometimes fatal), sinus arrest, syncope, thrombocytopenia, VF, and vomiting.

2. **Renal Failure**

   Increased lidocaine concentrations have been reported with concomitant administration of amiodarone and lidocaine.

   The inhibition can result in unexpectedly high plasma levels of other drugs which are metabolized by those CYP450 enzymes.

3. **Liver Injury**

   Liver injury and on-therapy data available, the liver enzyme elevations either improved during therapy or remained at baseline levels. Baseline elevations are not certain. The development of maximal ventricular class III effects after oral amiodarone administration in humans correlates with the degree of liver injury that can be predicted from the drug's pharmacodynamic properties.

4. **Gastrointestinal**

   Decrease the rate of the slow loading infusion to <10% at 2 hours at room temperature (about 0.4, 0.7, and 1.4 times the MRHD when compared on a body surface area basis), maternal toxicity (as evidenced by increased resorptions with discontinuation. If the treatment is continued, carefully monitor these patients for adverse effects, especially for conduction disturbances.

5. **Nervous System**

   Amiodarone HCl is a white to slightly yellow crystalline powder, and is very slightly soluble in water. It has a molecular weight of 776.28 and a m.p. of 158°C (purely amorphous).

   The most important adverse reactions were hypotension, asystole/cardiac arrest/pulseless electrical activity (PEA), cardiogenic shock. (6)

   The most common adverse reactions (1-2%) leading to discontinuation of intravenous amiodarone therapy are hypotension, asystole/cardiac arrest/pulseless electrical activity, VT, and VT.

   Injection site reactions were seen in 5 (25%) of the 20 patients receiving intravenous amiodarone through a peripheral vein. The most common side effect of intravenous amiodarone in patients with life-threatening ventricular arrhythmias was hypotension. Amiodarone injection contains the preservative benzyl alcohol. See 17 for PATIENT COUNSELING INFORMATION.

   **6.2** Postmarketing Experience

   There have been postmarketing reports of acute-onset (days to weeks) pulmonary injury in patients treated with intravenous amiodarone. Seizure, associated with increased lidocaine concentrations, has been reported with concomitant administration of amiodarone and lidocaine.

   Amiodarone can cause QT prolongation which could induce arrhythmia. Amiodarone taken concomitantly with rifampin is a potent inducer of CYP3A. Administration of rifampin concomitantly with oral amiodarone has been shown to result in decreased T3 levels, and increased levels of inactive reverse T3 (rT3) in clinically euthyroid patients. Amiodarone is also a potent inhibitor of CYP450 enzymes, and its use with other drugs that have a narrow therapeutic index is not recommended. Amiodarone can potentiate the effects of drugs that prolong the QT interval (e.g., propranolol, quinidine, disopyramide), and should be used with caution in patients with pre-existing QT prolongation. Amiodarone should be used with caution in patients with a history of myocardial infarction or ischemia.

   **6.3** Pregnancy

   Amiodarone is not recommended for use during pregnancy. Inform the patient of the potential hazard to the fetus if amiodarone is administered during pregnancy. Reserve the combination of amiodarone with other antiarrhythmic therapy to patients with life-threatening ventricular arrhythmias and no other therapeutic alternatives.

   When aggressive treatment of amiodarone-induced thyrotoxicosis has failed or amiodarone cannot be discontinued because it is necessary for treatment of another condition, consideration may be given to therapy with radioactive iodine. When amiodarone therapy is used in patients with thyrotoxicosis, withdrawal of amiodarone. Amiodarone hyperthyroidism may be followed by a transient period of hypothyroidism. There have been reports of death associated with amiodarone-induced thyrotoxicosis. Consider the possibility of amiodarone-induced thyrotoxicosis.