Amiodarone Hydrochloride Injection USP

150mg/3ml

For Intravenous Infusion only

Composition:
Each ml contains:
Amiodarone Hydrochloride USP .... 50 mg
Water for injection USP ..... q.s.

INDICATIONS & USAGE:
Amiodarone hydrochloride injection is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy. Amiodarone also can be used to treat patients with VT/VF for whom oral amiodarone is indicated, but who are unable to take oral medication. During or after treatment with amiodarone, patients may be transferred to oral amiodarone therapy.
Use amiodarone for acute treatment until the patient's ventricular arrhythmias are stabilized. Most patients will require this therapy for 48 to 96 hours, but amiodarone may be safely administered for longer periods if necessary.

DOSAGE & ADMINISTRATION:
Amiodarone shows considerable interindividual variation in response. Although a starting dose adequate to suppress life-threatening arrhythmias is needed, close monitoring with adjustment of dose is essential. The recommended starting dose of amiodarone is about 1000 mg over the first 24 hours of therapy.

CONTRAINDICATIONS:
Amiodarone is contraindicated in patients with:
- Known hypersensitivity to any of the components of amiodarone hydrochloride injection, including iodine. Hypersensitivity reactions may involve rash, angioedema, cutaneous/mucosal hemorrhage (bleeding), fever, arthralgias (joint pains), eosinophilia (abnormal blood counts), urticaria (hives), thrombotic thrombocytopenic purpura, or severe periarteritis (inflammation around blood vessels).
- Cardiogenic shock
- Marked sinus bradycardia
- Second- or third-degree atrio-ventricular (AV) block unless a functioning pacemaker is available.

WARNINGS AND PRECAUTIONS:
Amiodarone should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.
Because of the long half-life of amiodarone and its metabolite desethylamiodarone, the potential for adverse reactions or interactions, as well as observed adverse effects, can persist following amiodarone withdrawal.

DRUG INTERACTIONS
Pharmacodynamic Interactions
Drugs Prolonging the QT interval
Co-administration of drugs prolonging the QT interval (such as class I and III antiarrhythmics, lithium, certain phenothiazines, tricyclic antidepressants, certain fluoroquinolone and macrolide antibiotics, azole antifungals, halogenated inhalation anesthetic agents) increases the risk of Torsade de Pointes. In general, avoid concomitant use of drugs that prolong the QT interval.

Drugs That Slow Heart Rate
Concomitant use of drugs with depressant effects on the sinus and AV nodes (e.g., digoxin, beta blockers, verapamil, diltiazem, ivabradine, clonidine) can potentiate the electrophysiologic and hemodynamic effects of amiodarone, resulting in bradycardia, sinus arrest, and AV block. Monitor heart rate in patients on amiodarone and concomitant drugs that slow heart rate.

Pharmacokinetic Interactions
Effect of Other Drugs on Amiodarone
Amiodarone is metabolized to the active metabolite desethylamiodarone (DEA) by the cytochrome P450 (CYP450) enzyme group, specifically CYP3A and CYP2C8.
Amiodarone has the potential for interactions with drugs or substances that may be substrates, inhibitors or inducers of CYP450 enzymes (e.g., inhibitors such as protease inhibitors, grapefruit juice, certain fluoroquinolone and macrolide antibiotics, azole antifungals and inducers such as St. John's Wort) or P-glycoprotein. In view of the long and variable half- life of amiodarone, potential for drug interactions exists not only with concomitant medications but also with drugs administered after discontinuation of amiodarone.
Patients should avoid grapefruit juice beverages while taking amiodarone because exposure to amiodarone is significantly increased

OVERDOSAGE:
There have been cases, some fatal, of amiodarone overdose. Effects of an inadvertent overdose of intravenous amiodarone include hypotension, cardiogenic shock, bradycardia, AV block, and hepatotoxicity. Treat hypotension and cardiogenic shock by slowing the infusion rate or with standard therapy: vasopressor drugs, positive inotropic agents, and volume expansion. Bradycardia and AV block may require temporary pacing. Monitor hepatic enzyme concentrations closely. Neither amiodarone nor DEA is dialyzable.

Storage:
Store protected from light at a temperature not exceeding 25°C.

Keep the medicine out of reach of children.

Presentation: A box of 5 x 3ml Ampoules.

Manufactured in India:
US Pharma®
(INDIA) Private Limited
Pioneering Excellence. Redefining Quality.
www.uspharma.in