

Material Safety Data Sheet

Amiodarone Hydrochloride Tablets

Strength: 200mg.
Strength: 200mg.

Pack Size: 30,60,1000 Tablets per bottle
Pack Size: Blister pack of 100 tablets

Revision No.: 00

EMERGENCY OVERVIEW

AMIODARONE HYDROCHLORIDE TABLETS contain Amiodarone and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name: AMIODARONE HYDROCHLORIDE TABLETS
Chemical Formula: $C_{25}H_{29}I_2NO_3.HCl$
Chemical Name: 2-butyl-3-benzofuranyl 4-[2-(diethylamino)-ethoxy]-3,5-diiodophenyl ketone hydrochloride
Therapeutic Category A new class of anti-arrhythmic drugs

Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, India
Contact for information: Tel.: +91 2717 250337 Fax: +91 2717 250319
Emergency telephone No. Tel.: +91 2717 250331, 250332, 250336

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Amiodarone HCl	Not Found	19774-82-4
Inactive Ingredients :		
Colloidal silicon dioxide,	Not Found	7621-86-9
Corn starch,	Not Found	9005-25-8
Lactose monohydrate,	Not Found	63-42-3
Magnesium stearate,	Not Found	557-04-0
Povidone	Not Found	9003-39-8
Sodium starch glycolate.	Not Found	9063-38-1

Material Safety Data Sheet

Amiodarone Hydrochloride Tablets

Strength: 200mg.
Strength: 200mg.

Pack Size: 30,60,1000 Tablets per bottle
Pack Size: Blister pack of 100 tablets

Revision No.: 00

Section 3. Health Hazards Information

Dose and Administration	Loading doses of 800 to 1,600 mg/day are required for 1 to 3 weeks (occasionally longer) until initial therapeutic response occurs. When adequate arrhythmia control is achieved, or if side effects become prominent, Amiodarone dose should be reduced to 600 to 800 mg/day for one month and then to the maintenance dose, usually 400 mg/day	
Adverse Effects	Common Adverse effects : Gastrointestinal: Nausea and vomiting. Dermatologic: Solar dermatitis/photosensitivity. Neurologic: Malaise and fatigue, tremor/abnormal involuntary movements, lack of coordination, abnormal gait/ataxia, dizziness, paresthesias. Gastrointestinal: Constipation, anorexia.	Thyroid: Hypothyroidism, hyperthyroidism. Ophthalmologic: Visual disturbances. Hepatic: Abnormal liver-function tests. Respiratory: Pulmonary inflammation or fibrosis. Other: Flushing, abnormal taste and smell, edema, abnormal salivation, coagulation abnormalities.
Over Dose Effect	There have been cases, some fatal, of Amiodarone overdose.	
Contraindications	Amiodarone is contraindicated in patients with cardiogenic shock; severe sinus-node dysfunction, causing marked sinus bradycardia; second- or third-degree atrioventricular block; and when episodes of bradycardia have caused syncope	
Pregnancy Comments	Amiodarone can cause fetal harm when administered to a pregnant woman.	
Pregnancy Category	D	

Section 4. First aid measures

General	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention
Overdose Treatment	In addition to general supportive measures, the patient's cardiac rhythm and blood pressure should be monitored, and if bradycardia ensues, a β -adrenergic agonist or a pacemaker may be used. Hypotension with inadequate tissue perfusion should be treated with positive inotropic and/or vasopressor agents. Neither amiodarone nor its metabolite is dialyzable.

Material Safety Data Sheet

Amiodarone Hydrochloride Tablets

Strength: 200mg.
Strength: 200mg.

Pack Size: 30,60,1000 Tablets per bottle
Pack Size: Blister pack of 100 tablets

Revision No.: 00

Section 5. Fire – fighting measures

Flash point	Not Found	Upper Flammable Limit:	Not Found
Auto-Ignition Temperature:	Not Found	Lower Flammable Limit:	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	Fire and Explosion Hazard	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.
Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.		

Section 6. Storage / Spill / Disposal Measures

Storage	Store at 20°-25°C (68°-77°F) Dispense in a tight, light-resistant container.
Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage using high efficiency vacuum cleaner. Avoid breathing dust.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

Material Safety Data Sheet

Amiodarone Hydrochloride Tablets

Strength: 200mg.

Pack Size: 30,60,1000 Tablets per bottle

Strength: 200mg.

Pack Size: Blister pack of 100 tablets

Revision No.: 00

Section 8. Physical and chemical properties

Appearance	Amiodarone Hydrochloride Tablets, 200 mg are white to off-white, round-shaped, flat beveled-edge, uncoated tablets with bisect on one side and other side is plain; one side of bisect is debossed with 'ZE' and other side is debossed with '65'.		
Solubility in water	No Data Available	Odour	Odourless
Boiling point	No Data Available	Melting Point	No Data Available
Evaporation rate	No Data Available	Vapour density	No Data Available
Reactivity in water	No Data Available	Evaporation rate	No Data Available
Percentage Volatile by volume	No Data Available	Specific gravity	No Data Available
Vapour pressure	No Data Available		
Other information	Amiodarone hydrochloride is a white to cream-colored crystalline powder. It is slightly soluble in water, soluble in alcohol and freely soluble in chloroform. It contains 37.3% iodine by weight.		

Section 9. Physical Hazards

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	Stable	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	Hazardous Reaction	No data available.
Incompatibilities	No data available.		

Section 10. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
Other	In pregnant rats and rabbits, Amiodarone hydrochloride in doses of 25 mg/kg/day had no adverse effects on the fetus. In the rabbit, 75 mg/kg/day caused abortions in greater than 90% of the animals. In the rat, doses of 50 mg/kg/day or more were associated with slight displacement of the testes and an increased incidence of incomplete ossification of some skull and digital bones; at 100 mg/kg/day or more, fetal body weights were reduced; at 200 mg/kg/day, there was an increased incidence of fetal resorption.

Material Safety Data Sheet

Amiodarone Hydrochloride Tablets

Strength: 200mg.

Pack Size: 30,60,1000 Tablets per bottle

Strength: 200mg.

Pack Size: Blister pack of 100 tablets

Revision No.: 00

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

Date of issue: 21/02/2009

Supersedes edition of: New Edition

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.