

Seneca # 199147



TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Amiodarone Hydrochloride Injection

1. PRODUCT IDENTIFICATION

Product Name Amiodarone Hydrochloride Injection
Product Use Medical Treatment; Antiarrhythmic
Manufacturer Teva Parenteral Medicines, Inc.
Address 11 Hughes
 Irvine, CA 92618-1902

Chemtrec Emergency No. 1-800-424-9300 (United States)
 1-202-483-7617 (International Collect)
Business Phone 1-800-729-9991
Website Address <http://www.tevusa.com>

Common Names Cordarone IV
Chemical Name (2-butyl-3-benzofuranyl) [4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl]
 methanone hydrochloride

Chemical Formula C₂₅H₂₉I₂NO₃ • HCl
Chemical Family Class III Antiarrhythmic
How Supplied 150mg/3mL in 3 mL vial; 450mg/9ml in 10 ml vial;
 900mg/18ml in 20 ml vial

Date of Preparation: July 31, 2000

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	% by wt	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA		IDLH	OTHER
			TLV	STEL	PEL	STEL		
Amiodarone HCl	19774-82-4	5	NE	NE	NE	NE	NE	NE
Benzyl Alcohol	100-51-6	2.02	NE	NE	NE	NE	NE	NE
Polysorbate 80	9005-65-6	10	NE	NE	NE	NE	NE	NE
Water (for injection)	7732-18-5	Balance	NE	NE	NE	NE	NE	NE

NE - Not Established

C - Ceiling Limit

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 - 1998 format

CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.

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3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Material is a clear, pale yellow solution. May be harmful if swallowed. Overexposure may cause damage to the liver, thyroid, lungs, cardiovascular and reproductive systems. Avoid exposure during pregnancy. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous injection under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes: Contact may cause irritation. Effects may include stinging, watering, and redness of the eyes and redness and a burning sensation on the skin. Photosensitivity of the skin and blue coloration of the nails may occur.

Ingestion: Although ingestion is not an anticipated route of occupational exposure, this material is moderately toxic and may be harmful if swallowed. Symptoms similar to those identified under injection may occur, including severe hypotension (low blood pressure).

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure (An explanation in lay terms):

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, cardiovascular effects such as hypotension, congestive heart failure, cardiac arrhythmias and severe bradycardia (slowing of heart rate) may occur. Effects on the central nervous system may include ataxia, depression, nightmares and hallucinations. Other effects may include nausea, vomiting, headaches, pulmonary fibrosis, hyper or hypothyroidism, decreased libido, photosensitivity and liver damage.

Cancer: No carcinogenicity studies were conducted with Amiodarone, however, animal studies suggest a carcinogenic potential to the thyroid (see Section 11).

Chronic: Corneal microdeposits and impaired vision may occur. This product has caused reproductive effects in animals (see Section 11).

Target Organs: This product may produce adverse effects on the liver, thyroid, lung and cardiovascular system (see Section 11).

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include liver, thyroid, lung and cardiovascular disorders.

4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

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4. FIRST-AID MEASURES cont.

Eye Exposure: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water for at least 15 minutes. Seek medical attention.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

5. FIRE-FIGHTING MEASURES

Flash Point: No data Autoignition Temperature: No data

Flammable Limits (in air by volume, %): Lower: No data Upper: No data

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK Carbon Dioxide: OK Halon: OK
Foam: OK Dry Chemical: OK Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: This material may burn, but will not ignite readily.

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8).

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Special Fire Fighting Procedures cont.: Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

NFPA HAZARD CLASS: Health: 2 (Moderate)
 Flammability: 0 (Least)
 Reactivity: 0 (Least)

6. ACCIDENTAL RELEASE MEASURES

Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay upwind and away from spill. This material may burn, but will not ignite readily. Keep all sources of ignition away from spill. The use of explosion-proof equipment is recommended. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify fire authorities and appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

7. HANDLING and STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from sources of ignition and any incompatible materials or conditions (see Section 10). Protect from light and excessive heat. Store at room temperature 15-25°C (59-77°F).

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

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8. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with an organic vapor cartridge may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

9. PHYSICAL and CHEMICAL PROPERTIES

Relative Vapor Density (air = 1):	ND	Evaporation Rate (n-BuAc=1):	ND
Specific Gravity (water = 1):	~1	Melting/Freezing Point:	ND
Solubility in Water:	Soluble	Boiling Point:	100°C (212°F)
Vapor Pressure, mm Hg @ 25°C:	ND	pH:	3.5 – 4.5
Odor Threshold: Odorless			
Appearance and Color: Clear, Pale Yellow Solution			

ND = No Data

10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility. This product would not be compatible with acids, bases, or oxidizing agents.

Hazardous Polymerization: Will not occur.

Conditions To Avoid: Protect from light and sources of ignition. Avoid contact with incompatible chemicals.



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11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Camiodarone

IV LD50(rat) = 170 mg/kg	Oral LD50(rat) >3000 mg/kg	IP LD50(rat) = 610 mg/kg
IV LD50(dog) = 5 mg/kg	Oral LD50(mouse) >3000 mg/kg	IP LD50 (mouse) 450 mg/kg
	Oral (LD50(dog) >5 mg/kg	

Suspected Cancer Agent: Oral administration of Camiodarone caused a statistically significant, dose-related increase in the incidence of thyroid adenomas in rats. This product as well as all components have **NOT** been identified as carcinogens by NTP, IARC or OSHA.

Irritancy of Product: This product may be irritating to contaminated skin, eyes and other tissues.

Sensitization to the Product: This product is not expected to cause sensitization although individual sensitivities may vary.

Target Organ(s): This product may cause cardiovascular effects such as hypotension, congestive heart failure, cardiac arrhythmias and severe bradycardia. Patients administered Camiodarone have demonstrated elevated liver enzymes as well as occasionally fatal hepatocellular necrosis. Some patients (2%) have reported adult respiratory distress syndrome including pulmonary fibrosis. Effects on the thyroid (hyper or hypothyroidism) have also been reported.

Reproductive Toxicity Information: Listed below is information concerning the effects of Camiodarone on human and animal reproductive systems. This material is classified as a Pregnancy Category D (Positive evidence of risk).

Mutagenicity: Studies performed (Ames, micronucleus and lysogenic induction tests) were negative.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Animal studies conducted with Camiodarone demonstrated congenital goiter/hypothyroidism and hyperthyroidism, as well as a variety of adverse effects (e.g., reduced fertility, fewer full-term fetuses, increased resorptions with concomitantly lower litter weights) in animals.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Camiodarone on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Camiodarone on plants or animals in the aquatic environment.



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13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

14. TRANSPORTATION INFORMATION

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

15. REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Camiodarone is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product contains a chemical known to the State of California to cause developmental and reproductive effects – Camiodarone (Amiodarone) Hydrochloride.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.



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ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):

CAUTION! MAY BE HARMFUL IF SWALLOWED. OVEREXPOSURE MAY CAUSE DAMAGE TO THE LIVER, LUNGS, THYROID, CARDIOVASCULAR AND REPRODUCTIVE SYSTEMS.

Camiodarone should be administered under the supervision of a qualified physician. Avoid over-exposure. Avoid exposure during pregnancy. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when handling Camiodarone. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

CANADIAN REGULATIONS:

Canadian DSL/NDL Status: Camiodarone is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

16. OTHER INFORMATION

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