



Material Safety Data Sheet

Dipyridamole Injection

1. PRODUCT IDENTIFICATION

Product Name Dipyridamole Injection
Product Use Medical Treatment: Anti-thrombotic, vasodilator
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.newsicor.com>

Common Names Persantine[®], Anginal[®], Cardoxin[®], Nadyl[®]
Chemical Name 2,6-Bis (diethanolamino)-4,8-dipiperidinopyrimido (5,4-d) pyrimidine
Chemical Formula C₂₄H₄₀N₈O₄
Chemical Family Platelet Inhibitor

How Supplied 2 mL and 10 mL vials

Date of Preparation: December 6, 2005

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	Wt%	EXPOSURE LIMITS IN AIR				
			ACGIH		OSHA		Other
			TLV	STEL	PEL	STEL	
Dipyridamole	58-32-2	<1	NE	NE	NE	NE	NE
Polyethylene Glycol 600	25322-68-3	5	NE	NE	NE	NE	NE
Tartaric Acid	87-69-4	<1	NE	NE	NE	NE	NE
Water for Injection	7732-18-5	Balance	NE	NE	NE	NE	NE

NE - Not Established C - Ceiling Limit * Innovator's Exposure Limit

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

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

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Material is a yellowish liquid. May cause damage to the liver. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

Dipyridamole Injection

3. HAZARD IDENTIFICATION cont...

Symptoms of Overexposure by Route of Exposure: This material is intended for 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, itching, and a burning sensation on the skin.

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, it is considered to be of low toxic based on animal data. Symptoms similar to those identified under injection may occur.

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. However, effects including headaches, dizziness, flushing, sweating, low blood pressure and abdominal pain may occur. See package insert for other 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, effects such as headaches, dizziness, flushing, sweating, low blood pressure and abdominal pain may occur.

Cancer: No evidence of carcinogenicity in animal studies (see Section 11).

Chronic: May cause adverse effect on the liver (see Section 11).

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include liver 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.

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.

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.

Dipyridamole Injection

7. HANDLING and STORAGE cont...

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Protect from light. Keep away from any incompatible materials or conditions (see Section 10). Store at temperatures between 15-25°C (59-86°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.

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 a type 95 filter 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):	Not available	Evaporation Rate (n-BuAc=1):	~1
Specific Gravity (water = 1):	~1 @ 20°C	Melting/Freezing Point:	Not applicable
Solubility in Water:	Insoluble	Boiling Point:	~100°C (212°F)
Vapor Pressure, mm Hg @ 25°C.	Not available	pH:	2.2-3.2
Odor Threshold: Odorless			
Appearance and Color: Yellowish liquid			

ND = No Data

Dipyridamole Injection

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. Keep away from water reactive chemicals.

Hazardous Polymerization: Will not occur.

Hazardous Combustion Products: Heat may cause product to decompose, destroying the product or producing toxic fumes.

11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Dipyridamole, the active ingredient

Oral LD50(rat) = 8.4 g/kg	Subcutaneous LD50(rat) = 1.65 g/kg
Oral LD50 (mouse) = 2.15 g/kg	Subcutaneous LD50(mouse) = 2.7 g/kg
Oral LD50 (rabbit) = 4.25 g/kg	IP LD50 (mouse) = 150 mg/kg
IV LD50(rat) = 195 mg/kg	IV LD50(mouse) = 85 mg/kg
IP LD50(rat) = 1.26 g/kg	

Suspected Cancer Agent: Not carcinogenic in the rat or mouse. It is not listed as carcinogenic by NTP, IARC or OSHA.

Irritancy of Product: This product is expected to be mildly irritating to eyes and skin.

Sensitization to the Product: No data are available to indicate it is a sensitizer.

Reproductive Toxicity Information: Listed below is information concerning the effects of Dipyridamole on human and animal reproductive systems. This material is classified as a Pregnancy Category B (No evidence of risk).

Mutagenicity: Not mutagenic in bacterial and mammalian cell systems.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Not a teratogen or developmental toxicant in rats, mice and rats. Used as an agent to prevent thrombotic events in the fetus. No significant effects on fertility in rats at doses up to 60 times recommended human dose; at 155 times the recommended human dose, there was an effect on implantation and live fetuses.

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



TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Dipyridamole Injection

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 Dipyridamole on plants or animals in the environment.

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

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: Dipyridamole 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 does NOT contain chemicals known to the State of California to cause cancer or reproductive effects.

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.



TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Dipyridamole Injection

CANADIAN REGULATIONS

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

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): May cause damage to the liver. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling. Avoid accidental injection. Do not eat, drink or smoke when handling. Clean up spills promptly.

16. OTHER INFORMATION

Issue Date: 11/19/07

Previous Issue Date: 12/06/06

The information in this document is believed to be correct as of the date issued. **HOWEVER, NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS EXPRESSED OR IS TO BE IMPLIED REGARDING THE ACCURACY OR COMPLETENESS OF THIS INFORMATION, THE RESULTS TO BE OBTAINED FROM THE USE OF THIS INFORMATION OR THE PRODUCT, THE SAFETY OF THIS PRODUCT, OR THE HAZARDS RELATED TO ITS USE.** This information and product are furnished on the condition that the person receiving them shall make his own determination as to the suitability of the product for his particular purpose and on the condition that he assume the risk of his use thereof.