



Material Safety Data Sheet

Enalaprilat Injection

1. PRODUCT IDENTIFICATION

Product Name Enalaprilat Injection
Product Use Medical Treatment: Hypertension
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 Vasotec I.V.[®]
Chemical Name 1-[N-[(S)-1-Carboxy-3-phenylpropyl]-L-alanyl]-L-proline dihydrate
Chemical Formula C₁₈H₂₄N₂O₅ · H₂O
Chemical Family Platelet Inhibitor

How Supplied 1.25 mg/mL in 1mL and 2mL vials

Date of Preparation: December 15, 2005

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	Wt%	EXPOSURE LIMITS IN AIR				
			ACGIH		OSHA		Other
			TLV	CEIL	PEL	STEL	
Enalaprilat	76420-72-9	<1	NE	NE	NE	NE	NE
Benzyl Alcohol	500-51-6	<1	NE	NE	NE	NE	NE
Sodium Chloride	7647-14-5	<1	NE	NE	NE	NE	NE
Sodium Hydroxide for pH adjustment	1310-73-2	<1	NE	2 mg/m3	2 mg/m3	NE	NE
Water for Injection	7732-18-5	Balance	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 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 clear, colorless liquid. Eye and skin irritant. May cause damage to the reproductive system, liver and kidneys. Harmful to the fetus. May cause allergic skin and/or respiratory reactions. Avoid exposure during pregnancy and while breastfeeding. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

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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 and swelling of the eyes and redness, itching, burning and skin damage. May cause allergic skin reactions.

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, sleepiness, edema, low blood pressure and increased serum potassium levels 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, sleepiness, edema, low blood pressure and increased serum potassium levels may occur.

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

Chronic: Overexposure may cause damage to the reproductive system, liver and kidneys (see Section 11).

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include reproductive, liver and kidney 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: Move victim away from exposure and into fresh air. If irritation or redness develops, 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.

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 any incompatible materials or conditions (see Section 10). Store below 30°C (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 100 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.

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9. PHYSICAL and CHEMICAL PROPERTIES

Relative Vapor Density (air = 1):	Not determined	Evaporation Rate (n-BuAc=1):	>1
Specific Gravity (water = 1):	~1	Melting/Freezing Point:	Not determined
Solubility in Water:	Soluble	Boiling Point:	~100°C (212°F)
Vapor Pressure, mm Hg @ 25°C.	Not determined	pH:	6.5-7.5
Odor Threshold: Odorless			

Appearance and Color: Clear, colorless liquid

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. Keep away from amphotericin B and phenytoin sodium.

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 Enalaprilate, the active ingredient

Oral LD50(rat) = 2973 mg/kg	Subcutaneous LD50(rat) = 1418 mg/kg
Oral LD50 (mouse) = 3507 mg/kg	Subcutaneous LD50(mouse) = 1160 mg/kg
IV LD50(rat) = 849 mg/kg	IV LD50(mouse) = 859 mg/kg

Suspected Cancer Agent: Negative in long-term cancer studies in rats dosed up to 90 mg/kg/day (150 times the maximum recommended human dose) or in male and female mice dosed up to 90 and 180 mg/kg/day (150 and 300 times the maximum recommended human dose), respectively. It is not listed as carcinogenic by NTP, IARC or OSHA.

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

Sensitization to the Product: Reported to be a skin sensitizer if repeatedly contacted.

Reproductive Toxicity Information: Listed below is information concerning the effects of Enalaprilat on human and animal reproductive systems. It is classified as a Pregnancy Category C (Risk Cannot be Ruled Out; First Trimester) and D (Positive Evidence of risk; Second Trimester) and is a potential reproductive toxicant, based on its classification as an angiotension-converting enzyme (ACE) inhibitor.



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11. TOXICOLOGICAL INFORMATION cont...

Mutagenicity: Negative in several short-term screening tests for genetic damage.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Negative for fertility impairment in rats dosed up to 90 mg/kg/day of enalapril. Negative in rats and rabbits at a dose up to 333 and 50 times the maximum recommended human dose, respectively. As an ACE inhibitor, enalapril can cause birth defects, fetal morbidity, and fetal death in women who are administered it during the second and third trimesters of pregnancy.

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 Enalaprilat on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Enalaprilat 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 Material 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



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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: Enalaprilat 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.

CANADIAN REGULATIONS

Canadian DSL/NDSL Status: Enalaprilat 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) Eye and skin irritant. May cause damage to the reproductive system, liver and kidneys. Harmful to the fetus. May cause allergic skin and/or respiratory reactions. Avoid exposure during pregnancy and while breastfeeding. 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

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