

Mesna Injection

**1. PRODUCT IDENTIFICATION**

**Product Name** Mesna Injection  
**Product Use** Medical Treatment: Hemorrhagic Cystitis Inhibitor  
**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** Mesnex®  
**Chemical Name** 2-Mercaptoethanesulfonic Acid Monosodium Salt  
**Chemical Formula** C<sub>2</sub>H<sub>5</sub>O<sub>3</sub>S<sub>2</sub> · Na  
**Chemical Family** Sulfhydryl (thiol)

**How Supplied** 100 mg/mL in 10 mL vial

**Date of Preparation:** December 12, 2005

**2. COMPOSITION AND INGREDIENTS**

CHEMICAL NAME	CAS#	Wt%	EXPOSURE LIMITS IN AIR				
			ACGIH		OSHA		Other
			TLV	STEL	PEL	STEL	
Mesna	19767-45-4	10.46	NE	NE	NE	NE	NE
Benzyl Alcohol	100-51-6	1.04	NE	NE	NE	NE	NE
Ethylenediaminetetra-Acetic Acid, Disodium Dihydrate	6381-92-6	0.026	NE	NE	NE	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 with a strong, garlic-like odor. May cause allergic skin reactions. 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 mild irritation. Effects may include stinging, watering, and redness to the eyes and redness, itching and a burning sensation to the skin. May cause allergic skin reactions.

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, it is considered to be practically non-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 headache, fatigue, nausea, vomiting, diarrhea, limb pain, hypotension and allergy 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 headache, fatigue, vomiting, nausea, diarrhea, limb pain, hypotension and allergy may occur.

Cancer: No data identified on the potential to cause cancer.

Chronic: None expected (see Section 11).

Other: Contains benzyl alcohol which is potentially toxic when administered locally to neural tissues. Benzyl alcohol has been reported to be associated with fatal "gaspings syndrome" in premature infants.

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

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**4. FIRST-AID MEASURES cont...**

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: Non-flammable      Autoignition Temperature: Not applicable

Flammable Limits (in air by volume, %): Lower: Not applicable    Upper: Not applicable

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

<u>Water Spray:</u> OK	<u>Carbon Dioxide:</u> OK	<u>Halon:</u> OK
<u>Foam:</u> OK	<u>Dry Chemical:</u> OK	<u>Other:</u> Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

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). 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 away from spill. 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. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

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**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. Protect from light. Keep away from any incompatible materials or conditions (see Section 10). Store at temperatures between 2-30°C (36-86°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.

**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:	6.5-8.5
Odor Threshold: Not determined			

Appearance and Color: Clear, colorless liquid with a strong garlic-like odor

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 strong oxidizers and cisplatin.

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 Mesna, the active ingredient

Oral LD50(rat) = 4.44 g/kg	IV LD50 (rat) = 1.51 g/kg	SubQ LD50 (rat) = 2.31 g/kg
IP LD50 (rat) = 1.25 g/kg	Oral LD50 (mouse) = 6.1 mg/kg	SubQ LD50 (mouse) = 1.2 g/kg
IP LD50 (mouse) = 2.01 g/kg	IV LD50 (mouse) 1.72 g/kg	

Suspected Cancer Agent: No data identified on the potential to cause cancer. 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: Allergy reported in clinical use.

Reproductive Toxicity Information: Listed below is information concerning the effects of Mesna on human and animal reproductive systems.



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### 11. TOXICOLOGICAL INFORMATION cont...

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

Embryotoxicity/Teratogenicity/Reproductive Toxicity: No data identified on the effects on fertility. Manufacturer reports it not to affect fetuses of rats or rabbits at doses of up to 1000 mg/kg/day. One literature report describes decreased fetal weight and extra ribs in rabbit fetuses after maternal treatment with 600 mg/kg/day. In either case, mesna has low potential to be a teratogen or developmental toxicant in humans occupationally.

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 Mesna on plants or animals in the environment.

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



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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: Mesna 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: Mesna 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 allergic skin reactions. 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: 12/11/05

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