TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Metoclopramide Hydrochloride Injection

1. PRODUCT IDENTIFICATION

Product Name	Metoclopramide Hydrochloride Injection
Product Use	Medical Treatment; Antiemetic
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	Reglan®
Chemical Name	2-methoxy-4-amino-5-chloro-N-(2-diethylaminoethyl) benzamide Hydrochloride monohydrate
Chemical Formula	$C_{14}H_{12}ClN_3O_2 \cdot HCl \cdot H_2O$
Chemical Family	Aromatic Carboxamide
How Supplied	5mg/mL in 2 mL vial
Date of Preparation:	January 27, 2006

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	% by wt	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA		IDLH	OTHE
			TLV	STEL	PEL	STEL		
Metoclopramide Hydrochloride	54143-57-6	<1	NE	NE	NE	NE	NE	NE
Sodium Chloride	7647-14-5	<1	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 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 solution. May cause damage to the neuromuscular system. May cause allergic skin reactions. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

3. HAZARD IDENTIFICATION cont…

Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous or intramuscular 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: Effects may include stinging, watering, redness and swelling to the eyes and redness, itching and a burning sensation to the skin. May cause allergic skin reactions.

Ingestion: Although ingestion is not an anticipated route of occupational exposure, the active ingredient, metoclopramide hydrochloride is toxic and may be harmful if swallowed. 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 nausea, vomiting, diarrhea, shaking, jitters, weakness, muscle fatigue, drowsiness, milk discharge from the breast, breast development in males, hyper and hypotension (high and low blood pressure) may occur. 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, nausea, vomiting, diarrhea, shaking, jitters, weakness, muscle fatigue, drowsiness, milk discharge from the breast, breast development in males, hyper and hypotension (high and low blood pressure) may occur.

Cancer: Animal studies suggest a possible carcinogenic potential (see Section 11).

Chronic: Metoclopramide Hydrochloride may cause reproductive effects (see Section 11).

Target Organs: This product may produce adverse effects on the neuromuscular system (see Section 11).

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

4. FIRST-AID MEASURES cont…

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: 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 upwind and 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. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify 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 any incompatible materials or conditions (see Section 10). Store at controlled room temperature between 15 and 30˚C (59-86˚F). Do not freeze. Do not store open single dose vials for later use as they contain no preservative. Discard unused portion.

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: The use of a face shield and/or chemical goggles to safeguard against potential eye contact, irritation, or injury is recommended.

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):	<1
Specific Gravity (water = 1):	~1	Melting/Freezing Point:	~0°C (32°F)
Solubility in Water:	Completely	Boiling Point:	~100°C (212°F)
Vapor Pressure, mm Hg @	ND	pH:	3.0 – 5.0
Odor Threshold: Odorless			
Appearance and Color: Clear, Colorless 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. Keep away from strong acids, caustics and oxidizers.

Hazardous Polymerization: Will not occur.

Conditions To Avoid: Protect from freezing. Heat may cause product to decompose, destroying the product or producing toxic fumes.

11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Metoclopramide Hydrochloride

SubQ (rat) = 475 mg/kg

Suspected Cancer Agent: An increase in mammary neoplasm has been found in rodents after chronic administration of metoclopromide, most likely due to increases in prolactin levels. This product has NOT been identified as a carcinogen by NTP, IARC or OSHA.

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

Sensitization to the Product: A few cases of allergic response following clinical administration have been reported.

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

Mutagenicity: Not mutagenic in Ames gene mutation assay.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Not a teratogen in rats, mice and rabbits. No reproductive toxicity studies performed. Hyperprolactinemia may be associated with menstrual disturbances and infertility in women. Amennorhea and galactorrhea in women and impotence in men have been reported to the manufacturer but the effect on fertility has not been determined.

Target Organ(s): Metoclopramide Hydrochloride has been associated tardive dyskinesia, a syndrome consisting of potential irreversible, involuntary dyskinetic movements may develop.

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 Metoclopramide Hydrochloride on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Metoclopramide Hydrochloride 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: Metoclopramide Hydrochloride 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 a chemical 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.

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

May cause damage to the neuromuscular system. May cause allergic skin reactions. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling. Metoclopramide Hydrochloride should be administered under the supervision of a qualified physician. Avoid over-exposure. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when handling Metoclopramide HydrochlorideClean up spills promptly.

15. REGULATORY INFORMATION cont…

CANADIAN REGULATIONS

Canadian DSL/NDSL Status: Metoclopramide Hydrochloride 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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