



Material Safety Data Sheet

Ondansetron Injection, USP

1. PRODUCT IDENTIFICATION

Product Name Ondansetron Injection , USP
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 Zofran® Injection
Chemical Name (±)1,2,3,9-tetrahydro-9-methyl-3-[(2-methyl-1H-imidazol-1-yl)methyl]-4H-carbazol-4-one, monohydrochloride, dihydrate

Chemical Formula C₁₈H₁₉N₃O * HCl * 2H₂O
Chemical Family Indoles
How Supplied 2 mL Single Dose Vial (SDV)
 20 mL Multiple Dose Vial (MDV)

Date of Preparation: January 9, 2007

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	EXPOSURE LIMITS IN AIR						
		Wt%		ACGIH		OSHA		Other
		SDV	MDV	TLV	STEL	PEL	STEL	
Ondansetron	103639-04-	0.20	0.20	NE	NE	NE	NE	30mcg/m3 TWA*
Sodium Chloride	7647-14-5	9	0.82	NE	NE	NE	NE	NE
Citric Acid Monohydrate	5949-29-1	0.5	0.05	NE	NE	NE	NE	NE
Sodium Citrate	6132-04-3	0.25	0.02	NE	NE	NE	NE	NE
Propylparaben	94-13-3	----	0.01	NE	NE	NE	NE	NE
Methylparaben	99-76-3	----	0.12	NE	NE	NE	NE	NE
Water (for injection)	7732-18-5	Balance	Balance	NE	NE	NE	NE	NE

NE - Not Established

*Exposure guideline of GlaxoSmithKline

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 clear solution. 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 intravenous use 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 of the eyes and redness and a burning sensation on the skin.

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, the active ingredient, Ondansetron Hydrochloride, is not toxic if ingested. 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 hypersensitivity (such as skin rash, hives, itching and breathing difficulties), headache, constipation, flushing and abnormal nervous system sensations 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 hypersensitivity (such as skin rash, hives, itching and breathing difficulties), headache, constipation, and flushing may occur.

Cancer: Ondansetron Hydrochloride has not demonstrated carcinogenic effects in laboratory animals (see Section 11)

Chronic: Based on animal data, Ondansetron Hydrochloride is not considered a reproductive toxicant (see Section 11).

Target Organs: No target organ effects expected.

Other Comments: Rare cases of hypersensitivity reactions, sometimes severe have been reported. Some reactions were accompanied by cardiopulmonary arrest, hypotension, shock, and breathing difficulties.

Pre-Existing Medical Conditions: None known.



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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. 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 sources of ignition and any incompatible materials or conditions (see Section 10).

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 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):	ND	Evaporation Rate (n-BuAc=1):	ND
Specific Gravity (water = 1):	ND	Melting/Freezing Point:	0°C (32°F)
Solubility in Water:	Soluble	Boiling Point:	100°C
Vapor Pressure, mm Hg @ 25°C.	ND	pH:	3.3-5.7
Odor Threshold: ND			
Appearance and Color: Clear 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.

Hazardous Polymerization: Will not occur.

Hazardous Combustion Products: Oxides of carbon.



TEVA PARENTERAL MEDICINES

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11. TOXICOLOGICAL INFORMATION

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

Oral LD50(rat) = 95 mg/kg Oral LD50(dog) > 45 mg/kg IV LD50(rat) = 20201 ug/kg
IV LD50(dog) > 15 mg/kg

Chronic Toxicity: No studies identified for Ondansetron Hydrochloride.

Carcinogenicity: Negative for carcinogenicity in rats and mice administered oral doses of up to 10 and 30 mg/kg/day, respectively. It is not listed as carcinogenic by NTP, IARC or OSHA.

Irritancy of Product: This product is not expected to be irritating to contaminated skin, eyes and other tissues.

Sensitization to the Product: A non-sensitizer to the skin.

Reproductive Toxicity Information: Listed below is information concerning the effects of Ondansetron Hydrochloride on human and animal reproductive systems. This material is classified as a Pregnancy Category B:

Mutagenicity: Negative in a battery of short-term screening tests for mutagenicity.

Embryotoxicity/Teratogenicity: No evidence of teratogenic effects in pregnant rats and rabbits given intravenous doses up to 4 mg/kg/day.

Reproductive Toxicity: Negative for fertility impairment in rats administered doses up to 15 and 30 mg/kg/day, respectively.

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 Ondansetron Hydrochloride on plants or animals in the environment. Due to the small product size and dilute concentration of the components, this product is not anticipated to cause adverse effects.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Ondansetron Hydrochloride on plants or animals in the aquatic environment. Due to the small product size and dilute concentration of the components, this product is not anticipated to cause adverse effects.



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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. TSCA Inventory Status: Ondansetron 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 which is known to the State of California to cause cancer, developmental or other 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.

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15. REGULATORY INFORMATION cont.-

CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: Ondansetron Hydrochloride 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):

Ondansetron 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 Ondansetron Hydrochloride. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

16. OTHER INFORMATION

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