



TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Fuconazole Injection, USP

1. PRODUCT IDENTIFICATION

Product Name Fluconazole Injection, USP
Product Use Medical Treatment; Antifungal Agent
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 Diflucan®
Chemical Name 2,4-difluoro- α, α^1 -bis(1H-1,2,4-triazol-1-ylmethyl)benzyl alcohol

Chemical Formula C₁₃H₁₂F₂N₆O
Chemical Family Synthetic triazole antifungal agent
How Supplied 200mg/100ml and 400mg/200ml in 100 and 200ml glass bottles
 200mg/100ml and 400mg/200ml in 100 and 250 mL medical solution bags

Date of Preparation: December 6, 2005

2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	% by wt	EXPOSURE LIMITS IN AIR					
			ACGIH		OSHA		IDLH	OTHE
			TLV	STEL	PEL	STEL		
Fluconazole	86386-73-4	0.2	NE	NE	NE	NE	NE	NE
Sodium Chloride	7647-14-5	0.9	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.

Fluconazole Injection, USP

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Material is a clear, colorless solution. Eye irritant. May be harmful if swallowed. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous 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: Fluconazole is irritating to eyes and slightly irritating to the skin. Eye contact may cause stinging, watering, redness, and swelling.

Ingestion: Although ingestion is not an anticipated route of occupational exposure, this material is moderately toxic and may be harmful if swallowed. Symptoms similar to those identified under injection may occur, including nausea, vomiting and abdominal pain.

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 and abdominal pain 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, burning sensation, nausea, vomiting, diarrhea, headache and abdominal pain may occur.

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

Chronic: Fluconazole has caused reproductive and developmental effects in some animals (see Section 11).

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

Other Comments: Clinically or potentially significant drug interactions between Fluconazole and the following agents/classes have been observed: Oral hypoglycemics, Coumarin-type anticoagulants, Phenytoin, Cyclosporine, Rifampin, Theophylline, Terfenadine, Cisapride, Astemizole, Rifabutin and Tacrolimus (see Physicians Desk Reference or package insert for details).

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

Fuconazole Injection, USP

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.

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.

<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.



TEVA PARENTERAL MEDICINES

Material Safety Data Sheet

Fluconazole Injection, USP

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):	ND	Melting/Freezing Point:	ND
Solubility in Water:	Soluble	Boiling Point:	100°C (212°F)
Vapor Pressure, mm Hg @ 25°C.	ND	pH:	4.0 – 8.0
Odor Threshold: Odorless			
Appearance and Color: Clear, Colorless Solution			

ND = No Data

10. STABILITY and REACTIVITY

Stability: For glass bottles: Store between 86°F (30°C) and 41°F (5°C). Protect from freezing. For medical solution bags (non-PVC flexible polymer bags): Store between 77°F (25°C) and 41°F (5°C). Brief exposure up to 104°F (40°C) does not adversely affect the product. Protect from freezing.

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility.

Hazardous Polymerization: Will not occur.

Conditions To Avoid: Protect from freezing.



TEVA PARENTERAL MEDICINES

Materials Safety Data Sheet

Fluconazole Injection, USP

11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Fluconazole

IV LD50(rat) >200 mg/kg	Oral LD50(mouse) = 1408 mg/kg	IP LD50(rat) >941 mg/kg
IV LD50(dog) >100 mg/kg	Oral LD50 (rat) = 1271 mg/kg	IP LD50(mouse) =1273 mg/kg
IV LD50(mouse) >200 mg/kg	Oral LD50 (dog) >300 mg/kg	

Suspected Cancer Agent: In long-term carcinogenicity studies in rats and mice, an increased incidence of hepatocellular adenomas (benign) was reported in male rats treated at 5 and 10 mg/kg/day. This product has NOT been identified as a carcinogen by NTP, IARC or OSHA.

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

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

Reproductive Toxicity Information: Listed below is information concerning the effects of Fluconazole on human and animal reproductive systems. This material is classified as a Pregnancy Category C (Risk to Fetus Cannot be Ruled-Out).

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

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Did not produce birth defects in rabbits given many times the maximum recommended human dose. Birth defects were noted in rats treated at many times the maximum recommended human dose. This may be associated with a species-specific estrogen lowering effect of fluconazole in rats. Did not impair fertility in rats at doses up to 20 mg/kg/day orally or 75 mg/kg/day parenterally. The onset of parturition and abnormal labor occurred at some of the higher doses tested. These effects are thought to be due to a species-specific estrogen lowering effect that has not been observed in women treated with fluconazole.

There are no adequate and well-controlled studies in pregnant women. There have been reports of multiple congenital abnormalities in infants whose mothers were being treated for 3 or more months with high dose (400-800 mg/day) of Fluconazole therapy for coccidioidomycosis (an unindicated use). The relationship between Fluconazole use and these events is unclear.

Target Organ(s): Fluconazole has been associated with rare cases of serious hepatic toxicity, including fatalities primarily in patients with serious underlying medical condition. In such cases, no obvious relationship to total daily dose, duration of therapy, sex or age of the patient has been observed. Fluconazole hepatotoxicity has usually, but not always, been reversible on discontinuation of therapy.

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



TEVA PARENTERAL MEDICINES

Materials Safety Data Sheet

Fluconazole Injection, USP

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 Fluconazole on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Fluconazole 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: Fluconazole is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.



TEVA PARENTERAL MEDICINES

Materials Safety Data Sheet

Fluconazole Injection, USP

15. REGULATORY INFORMATION cont...

U.S. REGULATIONS

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):

CAUTION! EYE IRRITANT. HARMFUL IF SWALLOWED. Fluconazole 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 Fluconazole. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

CANADIAN REGULATIONS

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

16. OTHER INFORMATION

Issue Date: 12/06/05

Previous Issue Date: 10/31/02

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.