

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** **Voriconazole for Injection**  
**Manufacturer Name:** Gland Pharma Limited  
**Address:** Survey No.: 143 - 148, 150 & 151, Near Gandimaisamma Cross Roads  
 D.P. Pally, Quthubullapur Mandal - Ranga Reddy District  
 Hyderabad, Andhra Pradesh 500 043  
 India  
**General Phone Number:** +91-40-30510999  
**General Fax Number:** +91-40-30510810  
**Emergency Phone Number:** +91-40-30510999 (Gland Pharma);  
**Distributor Name:** Fresenius Kabi USA, LLC  
**Address:** Three Corporate Drive  
 Lake Zurich, Illinois 60047  
**General Phone Number:** (847) 550-2300  
**Customer Service Phone Number:** (888) 386-1300  
**Health Issues Information:** (800) 551-7176  
**SDS Creation Date:** February 18, 2020  
**SDS Revision Date:** September 04, 2020

### SECTION 2 : HAZARD(S) IDENTIFICATION

**GHS Pictograms:**



**Signal Word:** DANGER.

**GHS Class:** Acute toxicity - Oral, Category 3  
 Carcinogenicity, Category 2  
 Reproductive toxicity, Category 2  
 Specific target organ toxicity - repeated exposure, Category 2

**Hazard Statements:** Toxic if swallowed.  
 Suspected of causing cancer.  
 Suspected of damaging fertility or the unborn child.  
 May cause damage to organs through prolonged or repeated exposure.

**Precautionary Statements:** Obtain special instructions before use.  
 Do not handle until all safety precautions have been read and understood.  
 Do not breathe dust/fume/gas/mist/vapours/spray.  
 Wash hands thoroughly after handling.  
 Do not eat, drink or smoke when using this product.  
 Use personal protective equipment as required.  
 IF exposed or concerned: Get medical advice/attention.  
 Store locked up.  
 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.  
 Rinse mouth.  
 Avoid release to the environment.  
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

**Emergency Overview:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

**Route of Exposure:** Inhalation Ingestion Eye contact Skin Absorption. Injection.

**Potential Health Effects:**

**Potential Health Effects:** Animal studies indicate that this material may cause adverse effects on the liver, the developing fetus. The most common adverse effects reported with clinical use of voriconazole include visual disturbance, elevations of liver function tests and skin rash. Voriconazole has been associated with photosensitivity skin reactions especially during long term therapy..

**Acute Health Effects:** This is a medicinal product that may affect body functions. When inside vials the hazard is considered negligible. May produce slight eye irritation.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Voriconazole	137234-62-9	200 mg/Vial by weight	629-701-5
Hydroxypropyl beta cyclodextrin	128446-35-5	3,200 mg/Vial by weight	

## SECTION 4 : FIRST AID MEASURES

<b>Eye Contact:</b>	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
<b>Skin Contact:</b>	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
<b>Ingestion:</b>	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
<b>Other First Aid:</b>	For Adverse Event Information, please call (800) 551-7176.

## SECTION 5 : FIRE FIGHTING MEASURES

<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.
<b>Lower Flammable/Explosive Limit:</b>	Not established.
<b>Upper Flammable/Explosive Limit:</b>	Not established.
<b>Fire Fighting Instructions:</b>	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
<b>Extinguishing Media:</b>	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Protective Equipment:</b>	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Hazardous Combustion Byproducts:</b>	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.
<b><u>NFPA Ratings:</u></b>	
<b>NFPA Health:</b>	2

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	Contain spills with an inert absorbent material such as soil, sand or oil dry.
<b>Methods for cleanup:</b>	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

## SECTION 7 : HANDLING and STORAGE

<b>Handling:</b>	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
<b>Storage:</b>	Keep container tightly closed. Keep container in a cool, dry, well-ventilated area. Protect from light and store at controlled room temperature 20° - 25°C (68° - 77°F). Refer to product packaging
<b>Work Practices:</b>	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
<b>Eye/Face Protection:</b>	Chemical splash goggles. Wear a face shield also when splash hazard exist.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

**Respiratory Protection:** No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (<http://www.cdc.gov/niosh/npptl/topics/respirators/>) for a list of respirator types and approved suppliers.

**Other Protective:** Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

## EXPOSURE GUIDELINES

### SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

**Physical State:** A lyophilized powder or cake  
**Color:** White to off-white  
**Boiling Point:** Not established.  
**Melting Point:** Not established.  
**Solubility:** Not established.  
**Vapor Density:** Not established.  
**Vapor Pressure:** Not established.  
**Percent Volatile:** Not established.  
**pH:** Not established.  
**Flash Point:** Not established.  
**Flash Point Method:** Not established.  
**Auto Ignition Temperature:** Not established.

### SECTION 10 : STABILITY and REACTIVITY

**Chemical Stability:** Stable under normal temperatures and pressures.  
**Hazardous Polymerization:** Not reported.  
**Incompatible Materials:** Acids, strong oxidizer.  
**Special Decomposition Products:** CO<sub>x</sub>, NO<sub>x</sub> and emits toxic fumes under fire conditions.

### SECTION 11 : TOXICOLOGICAL INFORMATION

**Eye:** May cause slight eye irritation.  
**Teratogenicity:** Animal studies indicate that this material may cause adverse effects on the liver, the developing fetus.  
**Voriconazole :**  
**RTECS Number:** UV9145000  
**Skin:** Dermal - Rat - > 2,000 mg/kg  
**Ingestion:** LD50 Oral - Rat - < 300 mg/kg  
**Reproductive Toxicity:** Suspected human reproductive toxicant

### SECTION 12 : ECOLOGICAL INFORMATION

**Ecotoxicity:** No ecotoxicity data was found for the product.  
**Environmental Stability:** No environmental information found for this product.

### SECTION 13 : DISPOSAL CONSIDERATIONS

**Waste Disposal:** Dispose of in accordance with Local, State, Federal and Provincial regulations.

### SECTION 14 : TRANSPORT INFORMATION

**DOT Shipping Name:** Not Regulated.  
**DOT UN Number:** Not Regulated.

## SECTION 15 : REGULATORY INFORMATION

TSCA Inventory Status: Listed

Canada DSL: Listed

### Voriconazole :

EC Number: 629-701-5

## SECTION 16 : ADDITIONAL INFORMATION

### HMIS Ratings:

HMIS Health Hazard: 2\*

HMIS Fire Hazard: 0

HMIS Reactivity: 0

HMIS Personal Protection: X

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### Disclaimer:

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