SAFETY DATA SHEET

Voriconazole Tablets 50 mg and 200 mg

EMERGENCY OVERVIEW

VORICONAZOLE TABLETS contain an active drug substance Voriconazole, USP and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral tablets.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	Voriconazole Tablets
Potencies	**:**	50 mg and 200 mg
Chemical Name	**:**	(αR,βS)-α-(2,4-difluorophenyl)-5-fluoro-β-methyl-α-(1*H*-1,2,4-triazol-1-ylmethyl)-4-pyrimidineethanol
Therapeutic Category	**:**	Antifungal agent
Product Use	**:**	Use in treatment of : • Invasive aspergillosis •Candidemia (nonneutropenics) and disseminated candidiasis in skin, abdomen, kidney, bladder wall, and wounds •Esophageal candidiasis •Serious infections caused by *Scedosporium apiospermum* and *Fusarium* species including *Fusarium solani*, in patients intolerant of, or refractory to, other therapy
Marketed by	**:**	**Ajanta Pharma USA Inc**. Bridgewater, NJ 08807. Made in India
Contact Information	**:**	855-664-7744

Section 2. Health hazards information

Potential Health Effects	**:**	**Inhalation:** Not expected to be hazardous in final pharmaceutical form. During manufacturing process dust may generate which may cause respiratory irritation.

Eye Contact: Not expected to be hazardous in final pharmaceutical form. During manufacturing process dust may generate which may cause eye irritation.
Skin Contact: Not expected to be hazardous in final pharmaceutical form. During manufacturing process dust may generate which may cause skin irritation.
Ingestion: Health injuries are not known or expected under normal use.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical form.

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Voriconazole	TWA 0.1 mg/m^3	137234-62-9

TWA: Time-Weighted Average

Inactive ingredients: Each film-coated tablet contains the following inactive ingredients include lactose monohydrate, pre-gelatinized starch, croscarmellose sodium, povidone, magnesium stearate and a coating containing hypromellose, titanium dioxide, lactose monohydrate and triacetin.

Section 4. First aid measures

This product in the final dosage form (tablets) does not pose a problem of exposure to active moieties, and does not cause inhalation, skin and eye irritation problem. The lose powder exposure hazards are during the manufacturing process.

Inhalation : If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin Contact : Rinse skin with soap and water. Get medical attention if irritation develops and persists.

Eye Contact : If the powder enters the eyes, wash victim's eyes under gently running water. Use sufficient force to keep eyelids open, have victim "roll" eyes and flush for at least 15 minutes. Get medical attention develop and persists.

Ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Medical Treatment : Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and

maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

Over dosage : In clinical trials, there were three cases of accidental overdose. All occurred in pediatric patients who received up to five times the recommended intravenous dose of voriconazole. A single adverse event of photophobia of 10 minutes duration was reported. There is no known antidote to voriconazole.
Voriconazole is hemodialyzed with clearance of 121 mL/min. The intravenous vehicle, SBECD, is hemodialyzed with clearance of 55 mL/min. In an overdose, haemodialysis may assist in the removal of voriconazole and SBECD from the body.

Section 5. Fire-fighting measures

Flash Point : Not Available.
Extinguishing Media : Use carbon dioxide, dry chemical, or water spray.
Special Fire Fighting Procedures : For single units (packages): No special requirements needed.

For larger amounts (multiple packages) of product: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

General Fire Hazards/ Hazardous Combustible Products : The drug substance in the formulation is assumed to be combustible and may produce Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds on ignition.

Section 6. Accidental release measures

Personal Precautions : For consumer use, no unusual precautions are necessary. In laboratory, medical or industrial setting wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions : Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Clean-up Methods : Collect and place it in a suitable, properly labeled container for recovery or disposal. In case of large spills, non-essential personnel should be evacuated from affected area. Report emergency situation immediately. Clean up operations should be undertaken by trained personnel.

Section 7. Handling and storage

Handling	**:**	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin and clothing. Avoid generating airborne dust.
Storage	**:**	Voriconazole tablets should be stored at 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits	**:**	TWA 0.1 mg/m^3
Engineering Controls	**:**	For consumer use, no unusual precaution are necessary for handling tablets. In laboratory, medical or industrial setting use appropriate ventilation.
Respiratory Protection	**:**	For consumer use, no unusual precaution are necessary for handling tablets. In laboratory, medical or industrial setting, if the applicable occupational exposure limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
Personal Protection	**:**	For consumer use, no unusual precaution are necessary for handling tablets. In laboratory, medical or industrial setting use goggles, lab coat and gloves.
Recommended Facilities	**:**	Eye wash, washing facilities
General hygiene considerations	**:**	Handle in accordance with good hygiene and safety practice.

Section 9. Physical and chemical properties

Appearance	**:**	**Voriconazole tablets 50 mg** is white, round-shaped, biconvex, film-coated tablets debossed with ‘V50’ on one side and plain on other side are supplied as 30 counts bottle (NDC 27241-062-03) **Voriconazole tablets 200 mg** is white, oval-shaped, biconvex, film-coated tablets debossed with 'V200' on one side and plain on other side are supplied as 30 counts bottle (NDC 27241-063-03).
Other Information	**:**	pKa value of voriconazole is 1.6.

Section 10. Stability and reactivity

Stability	**:**	Stable at ambient temperature
Incompatibility	**:**	As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition	**:**	Thermal decomposition products include oxides of nitrogen, carbon monoxide, carbon dioxide and halogen containing gases.
Conditions to Avoid	**:**	None known.

Section 11. Toxicological information

Acute toxicity	**:**	Rat/mouse oral LD 50 <300 mg/kg
Carcinogenesis (Duration, Species, Route, Dose, End Point, Effect(s))	**:**	2 year(s), Rat, Oral, 18 mg/kg/day, NOEL, Benign tumors, Liver 2 year(s), Mouse, Oral, 30mg/kg/day, NOAEL, Malignant tumors, Liver
Impairment of Fertility (Species, Route, Dose, End Point, Effect(s))	**:**	Rat, oral, 3 mg/kg/day, NOAEL, Fetotoxicity.

Section 12. Ecological information

Eco toxicity of drug substance: The drug substance in tablet dosage form is not expected to present significant adverse environmental effects.
In the finished product form: There is no potential for air borne contamination since the drug product is in consolidated and contended as film coated tablet dosage form.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard away from children's reach.

Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

DOT: Not regulated
IATA: Not regulated

Section 15. Regulatory information

DEA: Not available
FDA: Voriconazole tablets is an approved prescription medication

Inventory Status: Not available

Section 16. Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: April 07, 2022

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