SAFETY DATA SHEET

Valganciclovir Tablets, USP 450 mg

EMERGENCY OVERVIEW

VALGANCICLOVIR TABLET, USP contain an active drug substance Valganciclovir Hydrochloride 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	**:**	Valganciclovir Tablets, USP
Potencies	**:**	450 mg
Chemical Name	**:**	L-Valine, 2-[(2-amino-1,6-dihydro-6-oxo-9H-purin-9-yl) methoxy]-3-hydroxypropyl ester, monohydrochloride
Therapeutic Category	**:**	Anti-Viral
Product Use	**:**	Use for treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS), prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk in adult patients and prevention of CMV disease in kidney and heart transplant patients at high risk in pediatric patients.
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 dosage form. **Eye Contact**: Not expected to be hazardous in final pharmaceutical dosage form.

Skin Contact: Not expected to be hazardous in final pharmaceutical dosage form.

Ingestion: Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.

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

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Valganciclovir Hydrochloride, USP	0.008mg/m^3	175865-59-5

Inactive ingredients: Each tablet contains 496.3 mg of valganciclovir hydrochloride, USP (corresponding to 450 mg of valganciclovir), and the inactive ingredients microcrystalline cellulose, povidone, crospovidone and stearic acid. The film-coat applied to the tablets contains hypromellose, polyethylene glycol, titanium dioxide, iron oxide red and iron oxide yellow.

Section 4. First aid measures

This product in the final dosage form (coated tablets) does not pose a problem of exposure to active moieties, and does not cause inhalation, skin and eye irritation problem. In case of exposure to lose powder during the manufacturing process take following measures.

Eye Contact : Immediately flush eyes with water for at least 10 minutes and open eyelids forcibly. Get medical attention.

Skin Contact : Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing immediately. Do not use any solvents. Get medical attention if symptoms occur. Wash clothing before reuse.

Ingestion : Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. DO NOT induce vomiting unless directed to do so by medical personnel.

Inhalation : Remove to fresh air. If not breathing, give artificial respiration or oxygen by trained personnel. Get 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	**:**	Overdosage with valganciclovir could possibly result in increased renal toxicity. Because ganciclovir is dialyzable, dialysis may be useful in reducing serum concentrations in patients who have received an overdose of valganciclovir. Adequate hydration should be maintained. The use of hematopoietic growth factors should be considered.

Section 5. Fire-fighting measures

Flash Point	**:**	Not Available.
Extinguishing Media	**:**	Water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions.
General Fire Hazards/ Hazardous Combustible Products	**:**	Formation of toxic and corrosive combustion gases (ammonia, hydrogen chloride, nitrogen oxides) possible.
Special Fire Fighting Procedures	**:**	Wear self-contained pressurized breathing apparatus (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental release measures

Personal Precautions	**:**	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Prevent any exposure.
Environmental Protections	**:**	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Do not allow to enter drains or waterways.
Clean-up Methods	**:**	Wipe with a damp cloth and place in a closed container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Clean contaminated areas with little ethanol.

Additional Consideration for Large Spills	:	Non-essential personnel should be evacuated from the affected area. Report emergency situations immediately. Clean up operations should only 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. Use adequate ventilation. Minimize dust generation and accumulation.
Storage	:	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits	:	0.008 mg/m^3
Engineering Controls	:	For consumer use, no special precaution are necessary for handling packets. In laboratory, medical or industrial setting use appropriate ventilation.
Respiratory Protection	:	Respiratory protection is recommended as a precaution to minimize the exposure. For consumer use, no special precaution are necessary. However, for handling packets, in laboratory, medical or industrial setting use NIOSH/MSHA approved respirators for protection, if necessary.
Personal Protection	:	For consumer use, no special precaution are necessary. However, for handling packets in laboratory, medical or industrial setting use gloves as recommended.
Recommended Facilities	:	None

Section 9. Physical and chemical properties

Appearance	:	Valganciclovir tablets, USP are supplied as 450 mg, pink, film-coated biconvex oval tablets debossed with “VL” on one side and “450” on the other side.

Valganciclovir tablets, USP are supplied in bottles of 60 tablets with child-resistant closure (NDC 27241-158-60).

Other Information : Valganciclovir hydrochloride, USP is a white to off-white crystalline powder. Valganciclovir hydrochloride is a polar hydrophilic compound with a solubility of 70 mg/mL in water at 25°C at a pH of 7.0 and an n-octanol/water partition coefficient of 0.0095 at pH 7.0. The pKa for valganciclovir hydrochloride is 7.6.

Section 10. Stability and reactivity

Stability : Stable
Incompatibility : Strong oxidizing agents.
Hazardous Decomposition : Tends to racemise and hydrolyse quickly in neutral and basic aqueous solution.
Conditions to Avoid : Warm. Humidity. Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials.

Section 11. Toxicological information

Acute toxicity : LD_{50} > 2,000 mg/kg (oral, mouse)

Carcinogenesis : Carcinogenic

Mutagenesis : Mutagenic

Impairment of Fertility : Teratogenic and embryotoxic. May lower parental fertility.

Note : Causes testicular atrophy, renal and hematologic changes.

Section 12. Ecological information

Eco toxicity of drug substance : Avoid release into the environment. Barely toxic to aquatic life.

In the finished product form : There is no potential for air borne contamination since the drug substance is in consolidated form as tablets.

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. DO NOT FLUSH unused medications or POUR them down a sink or drain. At home: Dispose of these medicines in the household trash by removing them from their original containers and

mixing them with an undesirable substance, such as used coffee grounds or kitty litter. If pharmacy service available, return unused tablets to pharmacy for disposal. 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 for transport of dangerous goods.
IATA: Not regulated for transport of dangerous goods.
IMDG: Not regulated for transport of dangerous goods.

Section 15. Regulatory information

DEA: It is not a scheduled drug. Therefore, DEA regulation are not applicable.
FDA: Valganciclovir Tablets, USP is an approved prescription medication.

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 06, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION