# SAFETY DATA SHEET

**Valganciclovir for Oral Solution 50 mg/mL**

**EMERGENCY OVERVIEW**

VALGANCICLOVIR FOR ORAL SOLUTION contains 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 route.

WARNING: Accidental ingestion of large amounts may be harmful.

## Section 1. Identification of the substance

**Identification of the product**

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| **Product name** | **:** | Valganciclovir for Oral Solution |
| **Potencies** | **:** | 50 mg/mL |
| **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 (4 months to 16 years of age) and heart transplant patients (1 month to 16 years of age) at high risk in pediatric patients. |
| **Marketed by** | **:** | **Ajanta Pharma USA Inc**.<br>Bridgewater, NJ 08807.<br>Made in India |
| **Contact Information** | **:** | 855-664-7744 |

## Section 2. Health hazards information

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| **Potential Health Effects** | **:** | **Inhalation:** Not expected to be hazardous in final reconstituted pharmaceutical dosage form. |

**Eye Contact**: Not expected to be hazardous in final reconstituted pharmaceutical dosage form.

**Skin Contact:** Not expected to be hazardous in final reconstituted 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:** Valganciclovir is available as a powder for oral solution, which when constituted with water as directed contains 50 mg/mL valganciclovir free base. The inactive ingredients of Valganciclovir for oral solution are sodium benzoate, tartaric acid, povidone, sodium saccharin, mannitol and fruity flavoring (banana, peach and pineapple).
Composition of banana, peach and pineapple flavor powders: Maltodextrin, silicon dioxide, gum arabic (banana flavor powder and pineapple flavor powder), starch sodium octenyl succinate, triacetin and alpha-tocopherol (peach flavor powder).

## Section 4. First aid measures

This product in the reconstituted dosage form (oral solution) 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.

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| **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

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| **Flash Point** | : | Not Applicable. |
| **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

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| **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.

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| **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

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| **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. Use adequate ventilation. Minimize dust generation and accumulation. |
| **Storage** | : | Store dry powder 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].<br><br>Store constituted solution under refrigeration at 2°C to 8°C (36°F to 46°F) for no longer than 49 days. Do not freeze. |

## Section 8. Exposure controls/personal protection

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| **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

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| **Appearance (How Supplied)** | : | Supplied as a white to slightly yellow powder blend for reconstitution in an amber glass bottle and forms a colorless to brownish yellow fruity flavored solution |

after reconstitution. It is approximately 100 mL of solution after constitution. Each bottle can deliver up to a total of 88 mL of solution. Each bottle is enclosed in a gusset pouch individually packed in a carton and supplied with a bottle adapter and 2 oral dispensers with child-resistant closure (NDC 27241-159-19).

**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 in the closed packaged form. Precaution should be taken not to spill the powder mix on opening. There is no

potential for airborne contamination after reconstitution.

## 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. 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 for Oral Solution 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 07, 2022

## SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION