

SAFETY DATA SHEET

Section 1: Identification	
Material	Valganciclovir for Oral Solution 50 mg/ 1mL
Recommended use	Anti-viral
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
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	Valganciclovir Hydrochloride, USP
CAS	175865-59-5
Section 4: First-Aid 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.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration or oxygen by trained personnel. Get medical attention immediately.
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.

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.
Section 5: Fire-Fighting Measures	
Suitable 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 Precautions	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.
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. 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]. 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.
8. Exposure controls / personal protection	
Exposure Guidelines	0.008 mg/m ³
Engineering Measures	For consumer use, no special precaution are necessary for handling packets. In laboratory, medical or industrial setting use appropriate ventilation
Personal Protection	For consumer use, no special precaution are necessary. However, for handling packets in laboratory, medical or industrial setting use gloves as recommended.

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.
Section 9: Physical and Chemical Properties	
Physical State	Powder
Description	<p>White to slightly yellow powder blend for constitution, forming a colorless to brownish yellow tutti-frutti flavored solution. Available in glass bottles containing approximately 100 mL of solution after constitution. Each bottle can deliver up to a total of 88 mL of solution.</p> <p>Each bottle is supplied with a bottle adapter and 2 oral dispensers NDC 31722-837-10</p>
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	LD50 > 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 Considerations

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: Other Information, including date of preparation or last revision

Issue Date: 04-01-2023

Version: 00

Further information:

Revision date: NA

Revision note: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.