Safety Data Sheet
Acyclovir Ointment, USP
Strength: 5% **Pack Size:** 15 gm, 30 gm. **NDC** 72578-082-01, 72578-082-06. **Revision No.:** 00

Emergency Overview

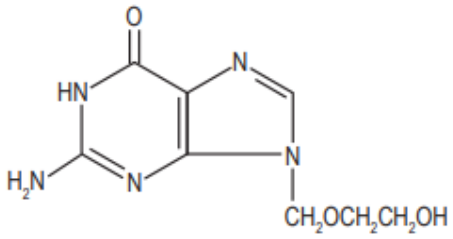
Acyclovir Ointment USP, 5% is a synthetic nucleoside analogue active against herpes viruses. Acyclovir Ointment USP, 5% is a formulation for topical administration. Each gram of Acyclovir Ointment USP, 5% contains 50 mg of acyclovir in a polyethylene glycol (PEG) base.

Section 1 : Identification

Product Name: Acyclovir Ointment USP, 5%

Formula: $C_8H_{11}N_5O_3$

Chemical Name: 2-amino-1,9-dihydro-9-[(2-hydroxyethoxy)methyl]-6H-purin-6-one



Molecular Weight: 225 g/mol

Description: Acyclovir Ointment USP, 5% is a synthetic nucleoside analogue active against herpes viruses. Acyclovir Ointment USP, 5% is a formulation for topical administration. Each gram of Acyclovir Ointment USP, 5% contains 50 mg of acyclovir in a polyethylene glycol (PEG) base.

Dosage forms and strengths: Apply sufficient quantity to adequately cover all lesions every 3 hours, 6 times per day for 7 days. The dose size per application will vary depending upon the total lesion area but should approximate a one-half inch ribbon of ointment per 4 square inches of surface area. A finger cot or rubber glove should be used when applying Acyclovir Ointment to prevent autoinoculation of other body sites and transmission of infection to other persons. And are available in two packs 15 gm and 30 gm.
Therapy should be initiated as early as possible following onset of signs and symptoms.

Manufacturer / supplier identification

Company	Cadila Healthcare Ltd. Ahmedabad, India
Address	Zydus Cadila, Topical Formulation facility. Plot No. 254, Opp. Laxmi Narayan Petrol Pump, N. H 8A, Ahmedabad -382210 India
Contact for information	Tel.:+91 2717-616430 Fax: +91 2717-616430
Emergency Telephone No	Tel.:+91 2717-616401
Recommended use / Therapeutic Category	Acyclovir Ointment 5% is indicated in the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infections in immunocompromised patients.
Restriction on Use / Contraindications	Acyclovir Ointment 5% is contraindicated in patients who develop hypersensitivity to the components of the formulation.

Section 2 : Hazard (s) Identification

Dose and Administration	Apply sufficient quantity to adequately cover all lesions every 3 hours, 6 times per day for 7 days. The dose size per application will vary depending upon the total lesion area but should approximate a one-half inch ribbon of ointment per 4 square inches of surface area. A finger cot or rubber glove should be used when applying Acyclovir Ointment to prevent autoinoculation of other body sites and transmission of infection to other persons. **Therapy should be initiated as early as possible following onset of signs and symptoms.**
Adverse effects	In the controlled clinical trials, mild pain (including transient burning and stinging) was reported by about 30% of patients in both the active and placebo arms; treatment was discontinued in 2 of these patients. Local pruritus occurred in 4% of these patients. In all studies, there was no significant difference between the drug and placebo group in the rate or type of reported adverse reactions nor were there any differences in abnormal clinical laboratory findings.
Over Dose Effect	Overdosage by topical application of Acyclovir Ointment 5% is unlikely because of limited transcutaneous absorption.

Pregnancy Comments

Teratogenic Effects

Pregnancy Category B

Acyclovir was not teratogenic in the mouse, rabbit, or rat at exposures greatly in excess of human exposure. There are no adequate and well-controlled studies of systemic acyclovir in pregnant women. A prospective epidemiologic registry of acyclovir use during pregnancy was established in 1984 and completed in April 1999. There were 749 pregnancies followed in women exposed to systemic acyclovir during the first trimester of pregnancy resulting in 756 outcomes. The occurrence rate of birth defects approximates that found in the general population. However, the small size of the registry is insufficient to evaluate the risk for less common defects or to permit reliable or definitive conclusions regarding the safety of acyclovir in pregnant women and their developing fetuses. Systemic acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:

It is not known whether topically applied acyclovir is excreted in breast milk. Systemic exposure following topical administration is minimal. After oral administration of Acyclovir, acyclovir concentrations have been documented in breast milk in 2 women and ranged from 0.6 to 4.1 times the corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg per day. Nursing mothers who have active herpetic lesions near or on the breast should avoid nursing.

Geriatric Use

Clinical studies of Acyclovir Ointment did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Systemic absorption of acyclovir after topical administration is minimal

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Section 3: Composition / information on ingredients

Each gram contains:	Active: 50 mg acyclovir in a polyethylene glycol base

Section 4: First -aid measures

General	Not Available.
Inhalation	If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if symptoms occur.
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person. If swallowed, rinse mouth with water (only if the person is conscious). Get medical attention if symptoms occur.
Most important symptoms and effects, both acute and delayed	Not available.
Indication of any immediate medical attention and special treatment needed	Treat symptomatically.

Section 5: Fire -fighting measures

General fire hazards	This product will support combustion at elevated temperatures.
Extinguishing media **Suitable extinguishing Media**	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing Media	Do not use water jet as an extinguisher, as this will spread the fire.
Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed.
Advice for firefighters **Special protective equipment for firefighters**	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting Procedures	Move containers from fire area if you can do so without risk.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
For emergency responders	Keep unnecessary personnel away.
Environmental precautions	Prevent further leakage or spillage if safe to do so.
Methods and material for containment and cleaning up	ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Use water spray to reduce vapors or divert vapors cloud drift. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use.

Section 7: Handling and Storage

Precautions for Safe Handling:	Avoid prolonged exposure. Use care in handling / storage. Avoid contact with ignition sources.
Conditions for safe storage, including any incompatibilities	Store in accordance with local/regional/national/international regulation. Store away from Incompatible materials. Keep away from heat, sparks and open flame.
Storage Conditions	Store at 15° to 25°C (59° to 77°F) in a dry place.

Section 8: Exposure controls/personal protection

Biological Limit Values: No biological exposure limits noted for the ingredient(s).

Recommended monitoring Procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

Occupational exposure limits

GSK

Components	Type	Value
ACYCLOVIR (CAS 59277-89-3)	8 HR TWA	5000 mcg/m3
	OHC	1

Appropriate engineering Controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. No special engineering controls are required. Local exhaust ventilation (LEV) is recommended. Only authorized personnel may enter the working area.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapors of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (e.g. EN 14387).

Section 9: Physical and chemical properties

Colour White.
Physical State (liquid/solid/gas): Semi-solid
Odour Not available.
Odour threshold Not available.
pH Not applicable.
Melting point/freezing point Not available.

Section 10: Stability and reactivity

Reactivity: The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical Stability: Not available.

Possibility of Hazardous Reactions: No dangerous reaction known under conditions of normal use.

Conditions to Avoid: Contact with incompatible materials. Heat, flames and sparks.

Incompatible Materials: None known.

Hazardous Decomposition Products: Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

Section 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion Based on available data, the classification criteria are not met.

Inhalation Based on available data, the classification criteria are not met.

Skin contact Based on available data, the classification criteria are not met.

Eye contact May be irritating to eyes.

Acute toxicity Based on available data, the classification criteria are not met.

Components	Species	Test results
ACYCLOVIR (CAS 59277-89-3)		
Acute		
Inhalation		
LC50	Rat	> 15.1 mg/l, 4 hours
Oral		
LD50	Rat	> 20 g/kg

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Irritation Corrosion - Skin
ACYCLOVIR
Acute dermal irritation, Tested at 5% in a cream; Irritation Index 0.02
Result: negative
Species: Rabbit

Serious Eye Damage/Eye Irritation: Based on available data, the classification criteria are not met. May be irritating to eyes.

Eye
ACYCLOVIR
Acute ocular irritation
Result: negative
Species: Rabbit

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Based on available data, the classification criteria are not met.

Sensitisation
ACYCLOVIR

Carcinogenicity: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Based on available data, the classification criteria are not met.

Carcinogenicity

ACYCLOVIR	2 year bioassay Result: negative Species: Mouse 2 year bioassay Result: negative Species: Rat

Section 12: Ecological information

Toxicity Not expected to be harmful to aquatic organisms.

Persistence and Degradability: No data is available on the degradability of this product.

Bioaccumulative Potential: Not available.

Mobility in Soil:

Adsorption

Sludge/biomass distribution coefficient - log Kd	
ACYCLOVIR	2.33 - 2.37 Estimated
Soil/sediment sorption - log Koc	
ACYCLOVIR	2.6 - 2.64 Measured

Other Adverse Effects: Not available.

Section 13: Disposal consideration

Residual waste Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Section 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Section 15: Regulatory information

Generic Medicine. NDC no.: 72578-082-01 (15 gm), 72578-082-06 (30 gm).

Section 16: Other information

None

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

Date of issue: 06/06/2020 **Supersedes edition:** New Edition