MATERIAL SAFETY DATA SHEET (MSDS)

Acyclovir Capsules, USP 200 mg

Revision Date: 17-January-2023 Version 1.0

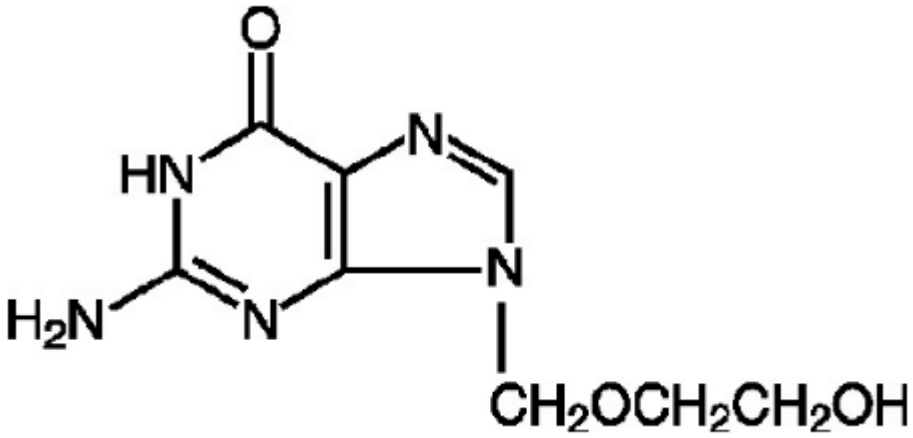
1. IDENTIFICATION

Identification of the product:

Product Name: Acyclovir Capsules, USP

Formula: $C_8 H_{11} N_5 O_3$

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



Manufacturer / supplier identification:

Company Name: Cadila Pharmaceuticals Limited

Address: 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.

Phone No.: 02714/221481

Fax No.: 02714/220315

Recommended use / Therapeutic Category:

Acyclovir is used to treat infections caused by certain types of viruses. It treats cold sores around the mouth (caused by herpes simplex), shingles (caused by herpes zoster), and chickenpox. This medication is also used to treat outbreaks of genital herpes.

Restriction on Use / Contraindications:

Acyclovir capsules are contraindicated for patients who develop hypersensitivity to acyclovir or valacyclovir.

2. HAZARDS IDENTIFICATION

Dose and Administration:

The most frequent adverse events reported during clinical trials of treatment of genital herpes with acyclovir 200 mg administered orally 5 times daily every 4 hours for 10 days were nausea and/or vomiting in 8 of 298 patient treatments (2.7%). Nausea and/or vomiting occurred in 2 of 287 (0.7%) patients who received placebo

The most frequent adverse events reported in a clinical trial for the prevention of recurrences with continuous administration of 400 mg (two 200-mg capsules) 2 times daily for 1 year in 586 patients treated with acyclovir were nausea (4.8%) and diarrhea (2.4%). The 589 control patients receiving intermittent treatment of recurrences with acyclovir for 1 year reported diarrhea (2.7%), nausea (2.4%) and headache (2.2%).

Overdoses involving ingestion of up to 100 capsules (20 g) have been reported. Adverse events that have been reported in association with overdosage include agitation, coma, seizures, and lethargy. Precipitation of acyclovir in renal tubules may occur when the solubility (2.5 mg/mL) is exceeded in the intratubular fluid. Overdosage has been reported following bolus injections or inappropriately high doses and in patients whose fluid and electrolyte balance were not properly monitored. This has resulted in elevated BUN and serum creatinine and subsequent renal failure. In the event of acute renal failure and anuria, the patient may benefit from hemodialysis until renal function is restored

Each acyclovir capsule intended for oral administration contains 200 mg of acyclovir. In addition, each capsule contains the following inactive ingredients: Lactose monohydrate, Corn starch, Sodium Lauryl Sulphate, magnesium stearate, FD & C Blue No. 2, Titanium Dioxide and Gelatin. Each capsule is printed with black pharmaceutical ink which contains

black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, shellac and strong ammonia solution

Adverse Effects:

Information for Patients: Patients are instructed to consult with their physician if they experience severe or troublesome adverse reactions, they become pregnant or intend to become pregnant, they intend to breastfeed while taking orally administered acyclovir, or they have any other questions.

Patients should be advised to maintain adequate hydration.

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Herpes Zoster: The most frequent adverse event reported during 3 clinical trials of treatment of herpes zoster (shingles) with 800 mg of oral acyclovir 5 times daily for 7 to 10 days in 323 patients was malaise (11.5%). The 323 placebo recipients reported malaise(11.1%).

Chickenpox: The most frequent adverse event reported during 3 clinical trials of treatment of chickenpox with oral acyclovir at doses of 10 to 20 mg/kg 4 times daily for 5 to 7 days or 800 mg 4 times daily for 5 days in 495 patients was diarrhea (3.2%). The 498 patients receiving placebo reported diarrhea (2.2%).

Over Dose Effect:

Overdoses involving ingestion of up to 100 capsules (20 g) have been reported. Adverse events that have been reported in association with overdosage include agitation, coma, seizures, and lethargy. Precipitation of acyclovir in renal tubules may occur when the solubility (2.5 mg/mL) is exceeded in the intratubular fluid. Overdosage has been reported following bolus injections or inappropriately high doses and in patients whose fluid and electrolyte balance were not properly monitored. This has resulted in elevated BUN and serum creatinine and subsequent renal failure. In the event of acute renal failure and anuria, the patient may benefit from hemodialysis until renal function is restored

Contraindications:

Acyclovir capsules are contraindicated for patients who develop hypersensitivity to acyclovir or valacyclovir.

Pregnancy Comments:

Acyclovir administered during organogenesis was not teratogenic in the mouse (450 mg/kg/day, p.o.), rabbit (50 mg/kg/day, s.c. and IV), or rat (50 mg/kg/day, s.c.). These exposures resulted in plasma levels 9 and 18, 16 and 106, and 11 and 22 times, respectively, human levels. There are no adequate and well-controlled studies 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. Acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category: B

3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Acyclovir	Not Found	59277-89-3
Lactose monohydrate	Not Found	10039-26-6
Corn Starch	Not Found	9005-25-8
Sodium Lauryl Sulphate	Not Found	151-21-3
Magnesium Stearate	Not Found	577-04-0

4. FIRST – AID MEASURES

General :

- **After inhalation:** Move to fresh air in case of accidental inhalation. assure fresh air breathing.
- **After skin contact:** Rinse skin with water/shower
- **After eye contact:** Rinse with water while holding the eyes wide open. Contact lenses should be removed.
- **After swallowing:** Rinse mouth out with water
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed-** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed-** No further relevant information available.

Overdose Treatment: Limited data are available related to overdosage in humans. If symptomatic hypotension occurs, initiate supportive treatment.

5. FIRE FIGHTING MEASURES

Extinguishing media:

Suitable extinguishing agents: Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder.

Special hazards arising from the substance or mixture Stable under normal conditions.

Advice for firefighters

Small amounts: Use normal individual fire protective equipment. Large amounts: Not

Protective equipment:

Hand protection : Gloves Skin and

Body protection : Lab coat

Respiratory protection : Quarter mask (DIN EN 140)

Specific hazards arising from the chemical: No additional information available.

Special protective equipment and precautions for firefighters: Use normal individual fire protective equipment

General fire hazards: No unusual fire or explosion hazards noted

6. ACCIDENTAL RELEASE MEASURES

Protective Precautions, Protective Equipment and Emergency Procedures: Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.

Environmental precautions: No additional information available

Method and Material Containment and cleaning up: Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.

7. HANDLING AND STORAGE

Storage:

Store at 15° to 25°C (59° to 77°F)

Protect from light, moisture, and excessive heat.

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure.

Keep This And All Medications Out Of The Reach Of Children.

Precautions for safe handling: Keep it dry & in a cool, well ventilated place away from heat. Store in original container.

Information about fire - and explosion protection: No special measures required.

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Respiratory Protection: Quarter mask (DIN EN 140).

Skin Protection: For prolonged or repeated skin contact use suitable protective gloves.

Eye/face protection: If contact is likely, safety glasses with side shields are recommended.

Protective Clothing: Protective clothing is not normally necessary; however it is good practice to use apron.

Biological limit values: No biological exposure limits noted for the ingredient(s).

Exposure guidelines: General ventilation normally adequate.

Thermal hazards: Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations:

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Engineering controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Description of Acyclovir Capsule: Hard gelatin capsule with a blue opaque cap and body. Each capsule is printed with "CP115" and "200" in black ink.

Solubility	Not available	**Odour**	Not available.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

10. STABILITY AND REACTIVITY

Conditions to avoid: Contact with incompatible materials.

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

Chemical stability: Material is stable under normal conditions.

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

Decomposition products: When heated to decomposition, emits dangerous fumes.

Incompatible materials: Strong Oxidizing agent.

11. TOXICOLOGY INFORMATION

General

Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Ingestion

Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Other: Not Available
Symptoms related to the physical, chemical and Toxicological characteristics: Not available
Information on toxicological effects Acute toxicity: Not available
Further information: Not available

12. ECOLOGICAL INFORMATION

Poorly soluble in water. No data available on ecotoxicity.

13. DISPOSAL CONSIDERATIONS

Dispose the waste in accordance with all applicable Federal, State and local laws.

14. TRANSPORT INFORMATION

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / ADN.

15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA on March 06, 2014 and the ANDA Number is 201445.

16. OTHER INFORMATION

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.

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

Cadila Pharmaceutical Limited reserves the right to revise this MSDS.