HETERO LABS LIMITED
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SAFETY DATA SHEET

Section 1: Identification	
Product information	
Product Name	Famciclovir Tablets, 125 mg, 250 mg and 500 mg
Active substance	Famciclovir
Intended Uses	Famciclovir Tablets is indicated for the treatment of recurrent herpes labialis.
Company Details	
Manufacturer	Hetero labs limited, Unit V, Polepally, Jadcherla Mahaboob Nagar-509 301, India.
Distributor	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Precautionary Statements	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Avoid contact during pregnancy/while nursing. Avoid release to the environment. Collect spillage.
Effects of Overexposure	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause increased severity of adverse effects. Individuals with underlying renal disease may be at risk for acute renal failure.
Hazard Statements	May be harmful if swallowed.
Potential Health hazards	**Inhalation:** Not expected to be an inhalation hazard in final pharmaceutical form. **Eye Contact:** Not expected to be a hazard to the eye in final pharmaceutical form. **Skin Contact**: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. **Ingestion:** May be harmful if ingested. Ingestion may cause headache, nausea, diarrhea and abdominal discomfort.

Section 3: Composition/Information on Ingredients	
Components	**CAS No.**
Famcyclovir	104227-87-4
Lactose Monohydrate	63-42-3
Sodium starch Glycolate	9063-38-1
Hydroxypropyl Cellulose	9004-64-2
Magnesium Stearate	557-04-0
Opadry White, IHS (YS -1 -7003)	117698-04-1

Section 4: First-Aid Measures	
General	Check the vital functions-Unconscious: maintain adequate airway and respiration. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
Inhalation	Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
Ingestion	If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice. Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. Rinse mouth with water-Immediately after ingestion: give lots of water to drink
Section 5: Fire-Fighting Measures	
Flammable Properties	Not available
Extinguishing Media	Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area
Protection of Firefighters	Wear full protective clothing and self-contained breathing apparatus.
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of nitrogen
Other information	Decontaminate protective clothing and equipment before reuse.
Section 6: Accidental Release Measures	
Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

Section 7: Handling and Storage	
Handling Precautions	Avoid exposure and formation of dust and aerosols. When handling broken or crushed tablets or capsules, ensure worker exposure is below the recommended exposure limit. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Container Requirements	Store in the original primary packaging as provided.
Storage Conditions	Store at 20º to 25º C (68º to 77ºF) [see USP Controlled Room Temperature].
Section 8: Exposure Controls/Personal Protection	
Exposure Limits **Engineering Controls**	None Not required when handling tablets or containers. Ventilation should be matched to conditions.
Respiratory Protection	Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.
Personal Protection	Not required when handling tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves
Recommended Facilities	Eye wash, washing facilities
Section 9: Physical and Chemical Properties	
General Information	
Appearance **Physical State** **Form**	 Solid Tablet
Odour	Not available
pH	Not available

Description & Availability	• 125 mg: Off white, round, biconvex, film coated tablets, debossed with 'I' on one side and '50' on the other side. They are available as follows Bottles of 30 tablets NDC 31722-706-30 Bottles of 60 tablets NDC 31722-706-60 Bottles of 100 tablets NDC 31722-706-01 Bottles of 500 tablets NDC 31722-706-05 Bottles of 1000 tablets NDC 31722-706-10 • 250 mg: Off white, round, biconvex, film coated tablets, debossed with 'I' on one side and '49' on the other side. They are available as follows Bottles of 30 tablets NDC 31722-707-30 Bottles of 60 tablets NDC 31722-707-60 Bottles of 100 tablets NDC 31722-707-01 Bottles of 500 tablets NDC 31722-707-05 Bottles of 1000 tablets NDC 31722-707-10 • 500 mg: Off white, oval, film coated, biconvex tablets, debossed with 'I' on one side and '48' on the other side. They are available as follows Bottles of 30 tablets NDC 31722-708-30 Bottles of 60 tablets NDC 31722-708-60 Bottles of 100 tablets NDC 31722-708-01 Bottles of 500 tablets NDC 31722-708-05 Bottles of 1000 tablets NDC 31722-708-10

Section 10: Stability and Reactivity

Stable under recommended storage conditions

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis	Two-year dietary carcinogenicity studies with famciclovir were conducted in rats and mice. An increase in the incidence of mammary adenocarcinoma (a common tumor in animals of this strain) was seen in female rats receiving the high dose of 600 mg/kg/day (1.1 to 4.5x the human systemic exposure at the recommended total daily oral dose ranging between 2000 mg and 500 mg, based on area under the plasma concentration curve comparisons [24 hr AUC] for penciclovir). No increases in tumor incidence were reported in male rats treated at doses up to 240 mg/kg/day (0.7 to 2.7x the human AUC), or in male and female mice at doses up to 600 mg/kg/day (0.3 to 1.2x the human AUC).

Mutagenesis	Famciclovir and penciclovir (the active metabolite of famciclovir) were tested for genotoxic potential in a battery of in vitro and in vivo assays. Famciclovir and penciclovir were negative in in vitro tests for gene mutations in bacteria (S. typhimurium and E. coli) and unscheduled DNA synthesis in mammalian HeLa 83 cells (at doses up to 10,000 and 5,000 mcg/plate, respectively). Famciclovir was also negative in the L5178Y mouse lymphoma assay (5000 mcg/mL), the in vivo mouse micronucleus test (4800 mg/kg), and rat dominant lethal study (5000 mg/kg). Famciclovir induced increases in polyploidy in human lymphocytes in vitro in the absence of chromosomal damage (1200 mcg/mL). Penciclovir was positive in the L5178Y mouse lymphoma assay for gene mutation/chromosomal aberrations, with and without metabolic activation (1000 mcg/mL). In human lymphocytes, penciclovir caused chromosomal aberrations in the absence of metabolic activation (250 mcg/mL). Penciclovir caused an increased incidence of micronuclei in mouse bone marrow in vivo when administered intravenously at doses highly toxic to bone marrow (500 mg/kg), but not when administered orally.
Impairment of Fertility	Impairment of fertility: Testicular toxicity was observed in rats, mice, and dogs following repeated administration of famciclovir or penciclovir. Testicular changes included atrophy of the seminiferous tubules, reduction in sperm count, and/or increased incidence of sperm with abnormal morphology or reduced motility. The degree of toxicity to male reproduction was related to dose and duration of exposure. In male rats, decreased fertility was observed after 10 weeks of dosing at 500 mg/kg/day (1.4 to 5.7x the human AUC). The no observable effect level for sperm and testicular toxicity in rats following chronic administration (26 weeks) was 50 mg/kg/day (0.15 to 0.6x the human systemic exposure based on AUC comparisons). Testicular toxicity was observed following chronic administration to mice (104 weeks) and dogs (26 weeks) at doses of 600 mg/kg/day (0.3 to 1.2x the human AUC) and 150 mg/kg/day (1.3 to 5.1x the human AUC), respectively. Famciclovir had no effect on general reproductive performance or fertility in female rats at doses up to 1000 mg/kg/day (2.7 to 10.8x the human AUC). Two placebo-controlled studies in a total of 130 otherwise healthy men with a normal sperm profile over an 8 week baseline period and recurrent genital herpes receiving oral famciclovir (250 mg twice daily) (n=66) or placebo

	(n=64) therapy for 18 weeks showed no evidence of significant effects on sperm count, motility or morphology during treatment or during an 8-week follow-up.
Animal Toxicology and/or Pharmacology	
	Juvenile toxicity study in rats: In juvenile rats, famciclovir was administered daily at doses of 0, 40, 125, or 400 mg/kg/day for 10 weeks beginning on post-partum Day 4. There were no treatment related deaths or clinical observations. The toxicity of famciclovir was not enhanced in juvenile rats compared to that in the adult animals.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Waste treatment methods

Additional information	Wash clothing and equipment after handling
Ecology - waste materials	Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A

DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 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.

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