

Getwell Pharmaceuticals 474, Udyog Vihar, Phase-V, Gurgaon - 122 016, Haryana, INDIA

Leucovorin Calcium Injection

Section I - IDENTITY

Common/Trade Name: Leucovorin Calcium Injection 15mg/2mL

(liquid filled) 50mg/5mL, 100mg/10mL

Chemical Names: L-Glutamic acid, N-[4-[[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-

6-pteridinyl)-methyl]amino]benzoyl]-,calcium salt (1:1)

Synonyms: Calcium Folinate, Folinic Acid, Calcium 5-formyltetrahydrofolate, Calcium Leucovorin,

Leucovorin Calcium Salt, Leucowel, Leucoget

Chemical Formula: C20H2CaN7O7

Manufacturer's Name: GETWELL PHARMACEUTICALS
Address: 474, UDYOG VIHAR, PHASE-V,

GURGAON - 122 016, HARYANA, INDIA

Telephone Number for Info.: + 91 124 4014 403 / 04

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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u> Leucovorin	<u>%</u>	CAS#	OSHA PEL	ACGIH TLV	Other Limits Recommended
Calcium	1.0	1492-18-8	NONE	NONE	NONE
Sodium Chloride	0.8	7647-14-5	NONE	NONE	NONE
Water for Injection	98.2		NONE	NONE	NONE

Leucovorin Calcium is a sterile injectable liquid drug provided in a vial.

Section III - HEALTH HAZARD DATA

Routes of Entry: Exposure is possible via inhalation and ingestion.

Health Hazard (Acute & Chronic): Product is drug used for treating nausea and support in patients

undergoing chemotherapy. May cause irritation and allergic reactions in

sensitized individuals who are allergic to folic acid.

Carcinogenicity: NTP? NO IARC Monographs? NONE

OSHA Regulated? NO

Signs & Symptoms of Exposure: Redness, irritation to eyes, skin, and respiratory tract, and allergy symptoms.

Medical Conditions Generally Aggravated by Exposure: None currently known.

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 minutes.

Skin Exposure: Wash skin with cool, soapy water.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. If person is conscious and medical assistance is not available, induce vomiting. Never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek attention of a physician immediately. If necessary, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not applicable LEL: NA UEL: NA

Flammable Limits: Not applicable

Extinguishing Media: Use water or an ABC multi-purpose extinguisher

Special Fire Fighting Procedures: As with all fires, evacuate persons to a safe area. Fire fighters

should wear self-contained breathing apparatus to avoid smoke inhalation.

Unusual Fire/Explosion Hazards: NONE

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Clean-up Leucovorin Calcium using water and absorb in absorbent materials. Dispose of according to local, state, and federal guidelines.

Release to Air: If aerosols are generated, reduce exposures by ventilating area; clean up spills immediately to prevent dusting.

Release to Water: Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning up spills. Double-gloving is strongly recommended. For large releases, a dust/mist respirator (N95) may be necessary if product is aerosolized.

Waste Disposal Method: Incineration in an approved incinerator is recommended. Refer to local, state, and federal guidelines.

Precautions to be taken in handling and storing: Store refrigerated 2-8 $^{\circ}$ C (36 – 46 $^{\circ}$ F);

Protect from light. **Other Precautions:** NONE

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses or goggles

Other Protective Clothing or Equipment: NONE

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while

handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: liquid Specific Gravity: 1.01

Appearance and Odor: clear and yellow **Melting Point:** Not available

Boiling Point: Not applicable **Evaporation Rate:** Not applicable

Vapor Pressure: Not applicable Solubility in Water: Very soluble in water

Vapor Density: Not applicable **pH**: 6.5 to 8.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable; store at 2-8°C (36-46°F). Protect from Light. Do Not Freeze.

Conditions to Avoid: Contact with strong oxidizers.

Incompatibility (Materials to Avoid): Avoid contact with incompatible materials and strong oxidizers.

Hazardous Decomposition or Byproducts: When heated, decomposition products of this chemical

may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, and carbon

dioxide.

Hazardous Polymerization: Will not occur

Section XI - TOXICOLOGICAL INFORMATION

For Leucovorin Calcium: MA0600500

LD50 intraveneous, mouse = 732 mg/kg

LD50 oral, rat = >8 gm/kg

LD50 oral, mouse = >7 gm/kg

LD₅₀ interperitoneal, mouse = 1036 mg/kg

LD₅₀ interperitoneal, rat = 1.063 mg/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Leucovorin Calcium. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator. Review local, state, and federal regulation for your regulatory area.

Section XIV - TRANSPORTATION INFORMATION

Leucovorin Calcium is not a DOT Hazardous Material. Leucovorin Calcium is not a DOT Marine Pollutant (49 CFR 171.101, Appendix B).

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO CERCLA listed?: NO RCRA listed?: NO

Section XVI - OTHER DATA

- 1. Use of this product should be through or under the direction of a physician. This MSDS does not address therapeutic use of this material.
- 2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.
- 3. GP Hazard Category Definitions (internal hazard ranking used by Getwell Pharmaceuticals):
 - 1 = Low Toxicity
 - 2= Moderate Toxicity
 - 3 = Potent or Toxic
 - 4 =Highly Potent or Toxic
 - 5 = Extremely Potent or Toxic
- 4. OEL=Occupational Exposure Limit. An internal limit set by Getwell Pharmaceuticals for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.

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