

Isovorin Injection

Preparation Date 20-Nov-2006

Revision Date 09-Sep-2008

Revision Number 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Name Isovorin Injection
Common Name Not available
Chemical Name Not applicable
Synonyms Not available
Product Use Pharmaceutical product
Classification Antidote to Folic Acid Antagonists

Supplier Wyeth
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2. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable
Calcium Levofolinate	1492-18-8	N/A	10 mg/ml	S13/37/39

3. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Biopharmaceutical liquid **Physical State** Liquid **Odor** Odorless

Potential Physical Hazards None known

Potential Health Effects

Eyes Not available
Skin Not available
Inhalation Not available
Ingestion The most common effects may include pyrexial reactions, anaphylactoid/anaphylactic reactions (including shock), leucopenia, mucositis, inflammation of the mouth, and diarrhea.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Metabolic system.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

4. FIRST AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide.
Unsuitable Extinguishing Media	Do NOT use water jet.
Fire Fighting	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides.
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8.
Environmental Precautions	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling	For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name	Exposure Guideline
Calcium Levofolinate	25 mcg/m ³

Engineering Controls Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
Other	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Biopharmaceutical liquid	Physical State	Liquid
Color	Clear	Odor	Odorless
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	Water Solubility	Soluble in water
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Density	Not available
Vapor Pressure	Not applicable		
Boiling Point	Not available	Autoignition Temperature	Not available
Flash Point	Not applicable	Melting Point	Not applicable
Flammability Limits in Air	Upper Not applicable	Lower Not applicable	
Explosion Limits	Upper Not applicable	Lower Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Calcium Levofolinate	
LD50 Oral	Not available

Acute Dermal Irritation	Not available
Primary Eye Irritation	Not available
Sensitization	Not available

Multiple Dose Toxicity

Calcium Levofolinate	
No Toxicologic Effect Dose/Species/Study Length:	No data available

Maximum Tolerated Dose (MTD), Oral

Calcium Levofolinate	
Carcinogenicity	Long-term animal toxicity studies to evaluate the carcinogenic potential have not been conducted.
Genetic Toxicity	No studies to assess the mutagenic potential have been performed.
Reproductive Toxicity	Reproductive studies in rat and rabbits have revealed no evidence of harm to the fetus.
Developmental Toxicity	Studies to evaluate the teratogenic potential have not been performed.

Calcium Levofolinate	
Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information	Not available
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Ecotoxicity	Not available
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13. DISPOSAL CONSIDERATIONS

Waste Disposal Method	Dispose of in accordance with local and national regulations.
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14. TRANSPORT INFORMATION

Transport Information	This material is not classified as hazardous for transport.
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15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with Directive 2001/58/EC.
List of References	See Patient Package Insert for more information.
Revision Summary	Changes to Section 8

Disclaimer:

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End of MSDS