FLUMAZENIL INJECTION, 0.1mg/mL USP

1. PRODUCT IDENTIFICATION

Common/Trade Name:	**Flumazenil Injection 0.1mg/mL**
How Supplied:	**Strength:**
Fill Volume 5 ml in 5 ml Clear Tubular Glass Vial USP Type I	0.1 mg/mL
Fill Volume 10 ml in 10 ml Clear Tubular Glass Vial USP Type I	0.1 mg/mL
Chemical Class:	Benzodiazepine antagonist
Chemical Name:	Ethyl 8-fluoro-5,6-dihydro-5-methyl-6-oxo-4H-imidazo-[1,5-a][1,4]benzodiazepine-3-carbonxylate
Formula:	$C_{15}H_{14}FN_3O_3$
Product Type:	Regulated Prescription Drug
Product Use:	Pharmaceutical, Injectable
Distributor Name:	CLARIS LIFESCIENCES INC
Distributor Address:	1445 US HIGHWAY 130, North Brunswick, NJ 08902
Manufacturer's Name:	CLARIS INJECTABLES LIMITED
Address:	CHACHARWADI-VASANA, AHMEDABAD - 382 213, INDIA.
Telephone Number For Information/ Medical Emergency	1-877-7CLARIS (1-877-725-2747)
Date Prepared:	17/09/2016

2. HAZARDOUS IDENTIFICATION

Emergency Overview:

Material is a clear, colorless solution. May be harmful if swallowed. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

Routes of Entry: Absorbed through skin. Eye contact. Ingestion.

General Effects of Exposure:

Acute Effects of Exposure:

The primary health effects anticipated in an occupational setting include mild irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, impaired vision, headaches, dizziness, drowsiness, fatigue, nausea, vomiting, lack of muscular coordination, increase or decrease in blood pressure, irregular heartbeat, chest pains and cardiac arrest may occur.

Chronic Effects of Exposure: No chronic adverse effects known.

Target Organs: This product may produce adverse effects on the cardiovascular system.
Other Comments: Use has been associated with the occurrence of seizures (see package insert).

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include respiratory disorders.

Ingestion:

Although ingestion is not an anticipated route of occupational exposure, this material is moderately toxic and may be harmful if swallowed. Symptoms similar to those identified under acute injection may occur, including impaired vision, headaches, and drowsiness, lack of muscular coordination, increase or decrease in blood pressure, chest pains and cardiac arrest.

Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous injection under the supervision of physicians.

Inhalation:

Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes:

Flumazenil may be mildly irritating to eyes and skin. Eye contact may cause stinging, watering, and redness. Skin contact may cause redness, itching, and burning.

Injection:

Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product.

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3. COMPOSITION INFORMATION

Component	mg/mL	CAS#	OSHA-PEL	ACGIH TLV
Flumazenil USP	0.1	78755-81-4	None	None
Methyl Paraben USP	1.8	99-76-3	None	None
Propyl Paraben USP	0.2	94-13-3	None	None
Sodium Chloride USP	9.0	7647-14-5	None	None
Edetate Disodium USP.	0.1	6381-92-6	None	None
Glacial Acetic Acid USP.	0.1	64-19-7	10 ppm	10 ppm
Hydrochloric Acid USP	q. s. to pH	7647-01-0	NE	None
Sodium Hydroxide USP	q. s. to pH	1310-73-2	NE	None
Water for Injections USP	q.s. to 1.0 ml	7732-18-5	None	None

NE- Not established

4. FIRST-AID MEASURES

Eye Exposure:

Move victim away from exposure and into fresh air. If irritation or redness develops, flush eyes with clean water and seek immediate medical attention. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water for at least 15 minutes. Seek medical attention.

Skin Exposure:

Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Ingestion:

If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

Inhalation:

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

NOTES TO HEALTH PROFESSIONALS:

See patient package insert in case pack/carton for complete information.

5. FIRE-FIGHTING MEASURES:

Flash Point : Not applicable

Auto ignition Temperature : Not applicable

Flammable Limits (in air by volume, %) :
LEL : Not applicable
UEL : Not applicable

Fire Extinguishing Equipment :Use extinguishing suitable for type of surrouindingfire.
Water spray: OK dry chemical: oK Halon: OK
Foam: OK Carbon Dioxide (CO_2). Other: Any ABC Class

Fire Fighting Equipment : Wear self-contained breathing apparatus and protective clothing.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

6. ACCIDENTAL RELEASE INFORMATION

Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay upwind and away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Like far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

7. HANDLING AND STORAGE

Work and Hygiene Practices:

As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug ampoules.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices:

Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from any incompatible materials or conditions (see Section 10). Store in dry place at room temperature. Product must not be used if it is discolored or contains a precipitate.

Protective Practices During Maintenance of Contaminated Equipment:

When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

Steps to be taken in case material is released or spilled:

Wear all necessary protective equipment including nitrile or latex gloves, protective clothing, and safety glasses. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated. Large spills may require the use of protective coveralls, boots, double gloves and SCBAs.

Waste Disposal Method:

Dispose of according to local, state, and federal guidelines. Incineration at a licensed facility is recommended.

Storage Temperature:

Employees must be trained to properly use the product. Ensure Ampoules are properly labeled. Store only in approved containers. Keep away from any incompatible materials or conditions (see Section 10). Store at controlled room temperature between 15 and 30°C (59-86°F). Do not freeze. Do not store open single dose vials for later use, as they contain no preservative. Discard unused portion.

Precautions to be taken in handling and storing:

Protect from light during storage. Avoid excessive heat. Protect from freezing. Do not remove unit from overwrap until ready for use. The overwrap is a moisture barrier.

Shelf Life: Do not use after expiration date.

Other Precautions: None identified.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION INFORMATION

Ventilation and Engineering Controls:

Use with adequate ventilation. Follow standard medical product handling procedures. Engineering controls are normally not needed during the normal use of this product.

Respiratory Protection: Respiratory protection is not needed during normal product use.

Eye Protection:

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Body Protection:

No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel:

Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	**Liquid**
Specific Gravity:	Approximate to water
Appearance:	Aqueous solution
Melting Point/Range:	Not applicable
Boiling Point/Range:	Not applicable
Evaporation Rate:	Approximate to water
Vapor Pressure:	Approximate to water
Solubility in Water:	Slightly soluble in acidic aqueous solutions, practically insoluble in water
Vapor Density:	Not Detected
pH	Between 3.4 and 4.6

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10. STABILITY AND REACTIVITY DATA

Stability : Stable under normal condition of storage and handling
Incompatibility (Materials to Avoid) : Not available
Hazardous Decomposition : Not available
Hazardous Polymerization : Not Applicable
Condition to avoid : Protect from refrigeration and freezing

11. TOXICOLOGICAL INFORMATION

Carcinogenicity:

This product has NOT been identified as a carcinogen by NTP, IARC or OSHA. No studies in animals have been performed to evaluate the carcinogenic potential of Flumazenil.

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

LD_{50}, oral, rat	4200 mg/kg
LD_{50}, IV, rat	85 mg/kg
LD_{50}, IV, Mouse	143 mg/kg
LD_{50}, oral, rabbit	2 gm/kg
LD_{50}, intraperitoneal, rabbit	4 gm/kg

12. ENVIRONMENTAL IMPACT INFORMATION

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

13. DISPOSAL INFORMATION

Waste Disposal :

Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal:

Dispose of container and unused contents in accordance with federal, state, and local regulations.

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14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS : Not regulated
IMDG STATUS : Not regulated
ICAO/IATA STATUS : Not regulated
Transport Comments : None

15. REGULATORY INFORMATION

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Flumazenil Injection USP	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

16. OTHER DATA

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