SECTION 01 – IDENTIFICATION

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Product Name: Epinephrine Injection, USP 1 mg / mL (1:1,000) Ampule for Intravenous Infusion

Synonyms: None

Therapeutic Use: Epinephrine is an alpha and beta adrenergic agonist indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

Description: Sterile aqueous solution that is colorless and nonpyrogenic. Preservative free, contains no sulfites. Solutions for intravenous use should be inspected visually for particulate matter and discoloration, whenever solution and container permit. Do not use if discolored or precipitated.

SECTION 02 – HAZARD(S) IDENTIFICATION

Eye: Causes irritation of the eye. Signs / symptoms may include redness, watering, and itching.

Skin: Causes irritation of the skin. Signs / symptoms may include localized redness, swelling, itching, and dryness. May be absorbed through skin and cause target organ effects.

Inhalation: May cause irritation of respiratory tract.

Ingestion: May cause irritation of the gastrointestinal tract.

SECTION 03 – COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredient	CAS Number	Amount
Epinephrine base (as the hydrochloride)	51-43-3	1 mg
Sodium Chloride	7647-14-5	9 mg
Hydrochloric Acid	7647-01-0	Used for pH adjustment
Water for Injection	7732-18-5	qs

SECTION 04 – FIRST AID MEASURES

Eyes: Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin: Wash skin with soap and water. Remove contaminated clothing and shoes. Wash clothing and thoroughly clean shoes before reuse. If irritation occurs or persists, get medical attention.

Inhalation: Remove to fresh air. If not breathing, start basic life support. Get medical attention immediately.

Ingestion: If ingestion occurs, flush mouth out with water and get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 05 – FIRE FIGHTING MEASURES

General Hazard: Not known.

Fire Fighting Instructions: Wear approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

Extinguisher to Use: Use carbon dioxide, dry chemical, foam, or water spray.

Flash Point: Not known.

Auto-ignition: Not known.

Flammability Limits: Not known.

Hazardous Combustion Products: Ordinary combustible material.

Minimum Explosive Concentration for Dust / Vapor: Not known.

SECTION 06 – ACCIDENTAL RELEASE MEASURES

Occupational Spill: Contain the source of spill or leak. Use an inert absorbent material for aqueous solutions to clean affected area and place in a labeled container for recovery or disposal. Clean spill area thoroughly with detergent and water.

Clean-up – Large Spill: Review Sections 02 and 08 for proceeding with the clean up. Contain the source of the spill or leak. Eliminate possible ignition sources and follow appropriate grounding procedures. Use an inert absorbent material for aqueous solutions to clean affected area and place in a labeled container for recovery or disposal. Close container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. Large spills may be subject to EPA/CERCLA Section 103 Release Report Requirements.

SECTION 07 – HANDLING AND STORAGE

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and / or vapors associated with product. Use with adequate ventilation.

Storage: Protect from light until ready to use. Do not refrigerate. Protect from freezing. Protect from alkalis and oxidizing agents.

Temperature Range: Store at room temperature, between 20°C to 25°C (68°F to 77°F).

SECTION 08 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Information: None established.

Ventilation: General room ventilation is adequate unless the process generates airborne dust or fumes.

Eye Protection: Wear ANSI approved chemical splash goggles or safety glasses.

Skin Protection: None required under normal and foreseeable conditions of use. Use coverall for clean up activities.

Hand Protection: Wear nitrile or latex gloves.

Respiratory Protection: None required under normal and foreseeable conditions of use. Use dust mask or approved respirator for dusty condition or when required.

SECTION 09 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Form:	Liquid solution.
Color:	Colorless.
Odor:	Odorless.
Molecular Weight:	183.2
Molecular Formula:	$C_9H_{13}NO_3$
pH:	2.2 to 5.0
Melting Point:	Not applicable.
Vapor Pressure:	Approximate to water.
Water Solubility:	Not applicable.
Solvent Solubility:	Aqueous solution.

SECTION 10 – STABILITY AND REACTIVITY

Reactivity:	Stable.
Conditions to Avoid:	Do not mix with other drugs. Exposure to light.
Incompatibilities:	None known.
Hazardous Polymerization:	Will not occur.
Hazardous Decomposition Products:	No data available. See section 05 under Hazardous Combustion Products.
Oxidizing Properties:	No data available.
Explosive Properties:	None known or expected.

SECTION 11 – TOXICOLOGICAL INFORMATION

Adequate carcinogenesis studies have not been reported. An equivocal response of epinephrine was found when tested in Salmonella typhimurium strain TA 100 in the absence of metabolic activation system (S9) and negative In the presence of activation system (S9).

There are no data from either animal or human studies regarding potential for the impairment of fertility.

Epinephrine was associated with metabolic effects, decreased mesenteric, coronary and renal conductance in a sheep model of septic shock. Data from hemolysis study have shown that epinephrine at 1:1,000 dilution is non-hemolytic. Epinephrine infusion significantly increased the MAP (69 vs. 86 mmHg) and cardiac output (6.4 vs. 7.1 L/min) and decreased renal blood flow (330 vs. 247 mL/min).

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: No relevant studies identified.

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal Procedure: Incineration is the recommended means of disposal for this material. This material may also be disposed in landfills. Federal, State, Local environmental regulations and Site conditions may affect proper disposal.

SECTION 14 – TRANSPORT INFORMATION

Proper Shipping Name: Epinephrine Injection, USP 1 mg / mL (1:1,000)

General Shipping Instructions: Non-regulated.

SECTION 15 – REGULATORY INFORMATION

No data available.

State Right to Know: Refer to applicable state to determine applicability.

SECTION 16 – OTHER INFORMATION

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