SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Enoxaparin Sodium Injection (Pre-filled syringe)**
Product Use/Restriction:	Anticoagulant
Manufacturer Name:	Gland Pharma Limited
Address:	Survey No.: 143 - 148, 150 & 151, Near Gandimaisamma Cross Roads D.P. Pally, Quthubullapur Mandal - Ranga Reddy District Hyderabad, Andhra Pradesh 500 043 India
General Phone Number:	+91-40-30510999
General Fax Number:	+91-40-30510810
Emergency Phone Number:	+91-40-30510999 (Gland Pharma);
Distributor Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	May 30, 2019
SDS Revision Date:	February 19, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

Emergency Overview:	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
Route of Exposure:	Inhalation Ingestion Eye contact Skin Absorption. Injection.
Potential Health Effects:	
Eye:	Contact with eyes may cause irritation.
Skin:	May cause skin irritation.
Inhalation:	May cause irritation of respiratory tract.
Ingestion:	May cause irritation.
Signs/Symptoms:	Adverse reactions from prescribed doses include: fever, hemorrhage, nausea, hypochromic anemia, thrombocytopenia, edema and peripheral edema. The incidence of hemorrhagic complications during Enoxaparin sodium injection treatment has been low. During clinical trials with Enoxaparin sodium injection, moderate thrombocytopenia, defined as a platelet count between 100,000/mm3 and 50,000/mm3 occurred at a rate of 1.9% in patients given Enoxaparin sodium, 2.0% in patients given heparin, and 1.7% in patients given placebo following hip or knee replacement surgery. Other adverse effects that were thought to be possibly or probably related to treatment with Enoxaparin sodium injection, heparin or placebo in clinical trials with patients undergoing hip or knee replacement surgery, and that occurred at a rate of at least 2% in the enoxaparin group, are fever, hemorrhage, nausea, hypochromic anemia, edema and peripheral edema.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Enoxaparin sodium	9041-08-1	100 mg/mL, 150 mg/mL by weight	
Water for Injection	7732-18-5	Quantity Sufficient	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Note to Physicians:	Accidental overdosage following administration of Enoxaparin sodium injection may lead to hemorrhagic complications. This may be largely neutralized by the slow intravenous injection of protamine sulfate (1% solution). The dose of protamine sulfate should be equal to the dose of Enoxaparin sodium injection injected: 1 mg protamine sulfate should be administered to neutralize 1 mg Enoxaparin sodium injection. A second infusion of 0.5 mg/mg protamine sulfate per 1 mg of Enoxaparin sodium injection may be administered if the APTT measured 2 to 4 hours after the first infusion remains prolonged. However, even with higher doses of protamine, the APTT may remain more prolonged than under normal conditions found following administration of conventional heparin. In all cases, the anti-Factor Xa activity is never completely neutralized (maximum about 60%). Particular care should be taken to avoid overdosage with protamine sulfate. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis, have been reported with protamine sulfate, it should be given only when resuscitation techniques and treatment of anaphylactic shock are readily available. For additional information consult the labeling of Protamine Sulfate Injection, USP, products.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Enoxaparin sodium :

Guideline ACGIH: Not established.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Clear
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	5.5 - 7.5
Molecular Formula:	Mixture
Molecular Weight:	Variable.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from freezing.

SECTION 11 : TOXICOLOGICAL INFORMATION

Enoxaparin sodium :

Acute Toxicity:	A single subcutaneous dose of 46.4 mg/kg enoxaparin was lethal to rats. The symptoms of acute toxicity were ataxia, decreased motility, dyspnea, cyanosis and coma.
Chronic Effects:	None known.

Enoxaparin sodium :

RTECS Number:	MI0850000
Ingestion:	Oral - Rat LD50: >779000 iu/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: >5 gm/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 391821 iu/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 2800 mg/kg [Behavioral - convulsions or effect on seizure threshold] Intravenous. - Rat TDLo: 300 units/kg [Blood - hemorrhage Blood - change in clotting factors] Intravenous. - Guinea pig TDLo: 160 units/kg [Blood - change in clotting factors] Intravenous. - Rat TDLo: 84 ku/kg/28D (intermittent) [Musculoskeletal - other changes Nutritional and Gross Metabolic - changes in calcium Nutritional and Gross Metabolic - changes in phosphorus] Subcutaneous - Rat LD50: 46715 iu/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: >2500 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Human TDLo: 3600 units/kg/18D (intermittent) [Blood - hemorrhage Related to Chronic Data - death] Intraperitoneal. - Mouse LD50: >2500 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.

Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
IATA Shipping Name:	Non regulated.
IATA UN Number:	Non regulated.
IMDG UN Number :	Non regulated.
IMDG Shipping Name :	Non regulated.

SECTION 15 : REGULATORY INFORMATION

Enoxaparin sodium :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date:	May 30, 2019
SDS Revision Date:	February 19, 2024
SDS Revision Notes:	Overall SDS review - no changes to formulation. Revised the HMIS ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE).