

SAFETY DATA SHEET



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

Material	ARIXTRA INJECTION
Synonym(s)	ARIXTRA INJECTION 2.5 MG/0.5 ML * ARIXTRA INJECTION 5 MG/0.4 ML * ARIXTRA INJECTION 7.5 MG/0.6 ML * ARIXTRA INJECTION 10 MG/0.8 ML * NDC NO. 0007-3230-02 * NDC NO. 0007-3232-11 * NDC NO. 0007-3234-11 * NDC NO. 0007-3236-11 * FONDAPARINUX SODIUM, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

* 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
FONDAPARINUX SODIUM	114870-03-0	0.5	
NON-HAZARDOUS INGREDIENTS	Unassigned	99.5	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Caution - Pharmaceutical agent.</p> <p>Possible effects of overexposure in the workplace include: reduced blood coagulation; bleeding.</p> <p>Health effects information is based on hazards of components.</p> <p>Exposure might occur via ingestion; eyes; skin.</p>
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
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Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of anti-coagulant. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	This product is non-combustible, although the packaging is combustible.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Clean-up Methods	Spread an inert absorbent on the spill and place in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	FONDAPARINUX SODIUM
GSK Occupational Hazard Category	3
GSK Occupational Exposure Limit	50 mcg/m ³ (8 HR TWA)
ENGINEERING CONTROLS	
Exposure Controls	The GSK Exposure Control Matrix recommends controls which are effective only for dusts and solid particulates. Consult your local occupational hygiene specialist, or safety officer for effective controls for liquids, vapours, and gases.
Administrative	Entry to the working area should be controlled.

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Other Equipment or Procedures Wash hands and arms thoroughly after handling. Wear appropriate clothing to avoid skin contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Clarity Clear.
Colour Colourless.
Physical Form Liquid.

10. STABILITY AND REACTIVITY

Stability DO NOT FREEZE - dispose of properly if frozen.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects This product contains active ingredient(s) with the following activity: reduced blood coagulation.

Target Organ Effects No specific target organ effects have been identified.

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.
Inhalation Toxicity No studies have been conducted.
Skin Effects Irritation is not expected following direct contact.
Eye Effects Irritation is not expected following direct contact with eyes.

Sensitisation Sensitisation (allergic skin reaction) is not expected.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has had limited testing and no adverse environmental effects were observed in the tests conducted. This material is not expected to persist in the environment. Local regulations and procedures should be consulted prior to environmental release. Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Microbial Growth Inhibition This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.

Minimum Inhibition Concentration: > 1000 mg/l

MOBILITY

Solubility This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Volatility This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant > 9.67E+00 atm m³/mol, Calculated

Partitioning This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

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PERSISTENCE/DEGRADATION**Hydrolysis**

This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral: > 1 Years, Measured, pH 7 Buffer Solution

Biodegradation

This material is likely to rapidly undergo biotransformation by microorganisms. This material is likely to undergo mineralization by microorganisms.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements

Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling**Transport Information**

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)**Classification**

This product is classified as hazardous according to the OSHA Hazard Communication Standard.

Target Organ Statement

No specific target organ effects known.

Other US Regulations**TSCA Status**

Exempt

16. OTHER INFORMATION

References

GSK Hazard Determination

SDS Version Number

5

SDS Sections Updated**Sections**

COMPOSITION / INFORMATION ON INGREDIENTS

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

Subsections

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.