ENOXAPARIN SODIUM - enoxaparin sodium injection, solution
Italfarmaco SpA

ENOXAPARIN SODIUM injection, for subcutaneous and intravenous use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 11797-757-06

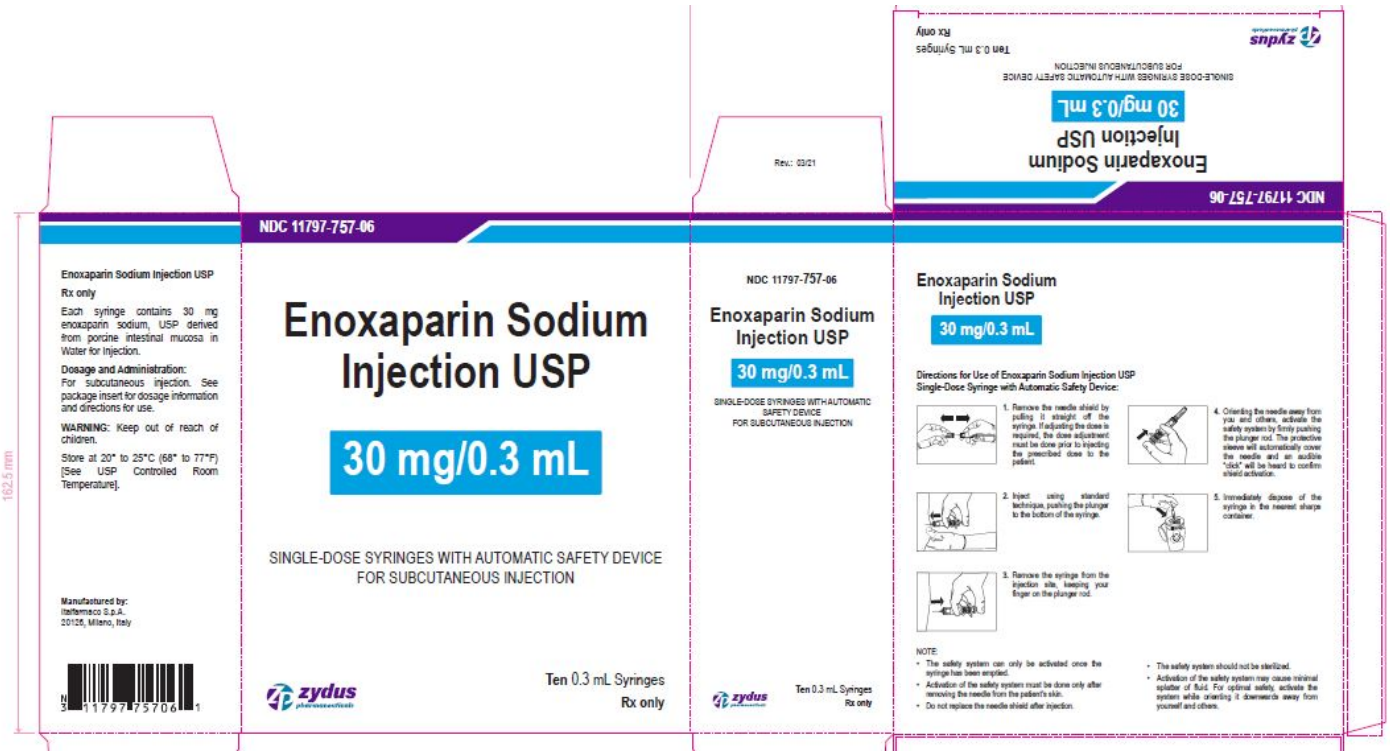
Enoxaparin Sodium Injection USP

30 mg/0.3 mL

SINGLE-DOSE SYRINGES WITH AUTOMATIC SAFETY DEVICE

FOR SUBCUTANEOUS INJECTION

Ten 0.3 mL Syringes



NDC 11797-758-06

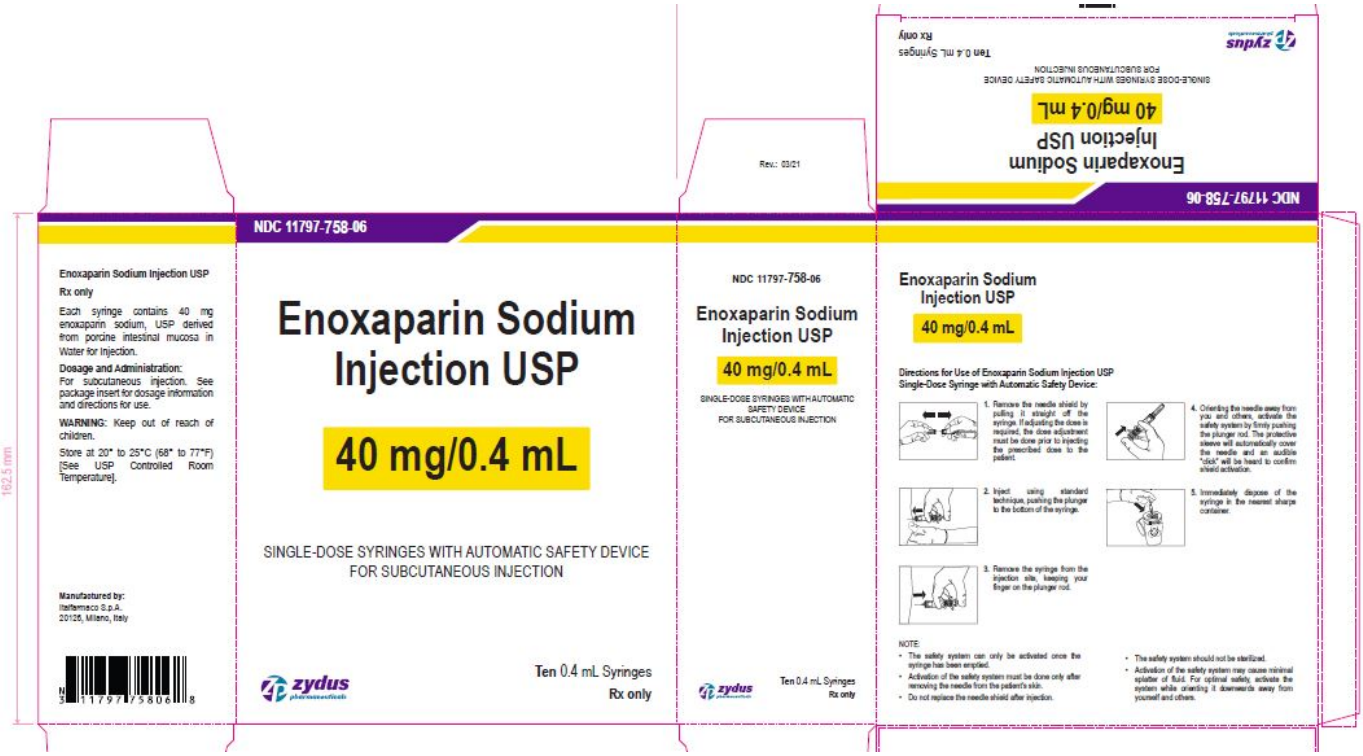
Enoxaparin Sodium Injection USP

40 mg/0.4 mL

SINGLE-DOSE SYRINGES WITH AUTOMATIC SAFETY DEVICE

FOR SUBCUTANEOUS INJECTION

Ten 0.4 mL Syringes



NDC **11797-759-06**

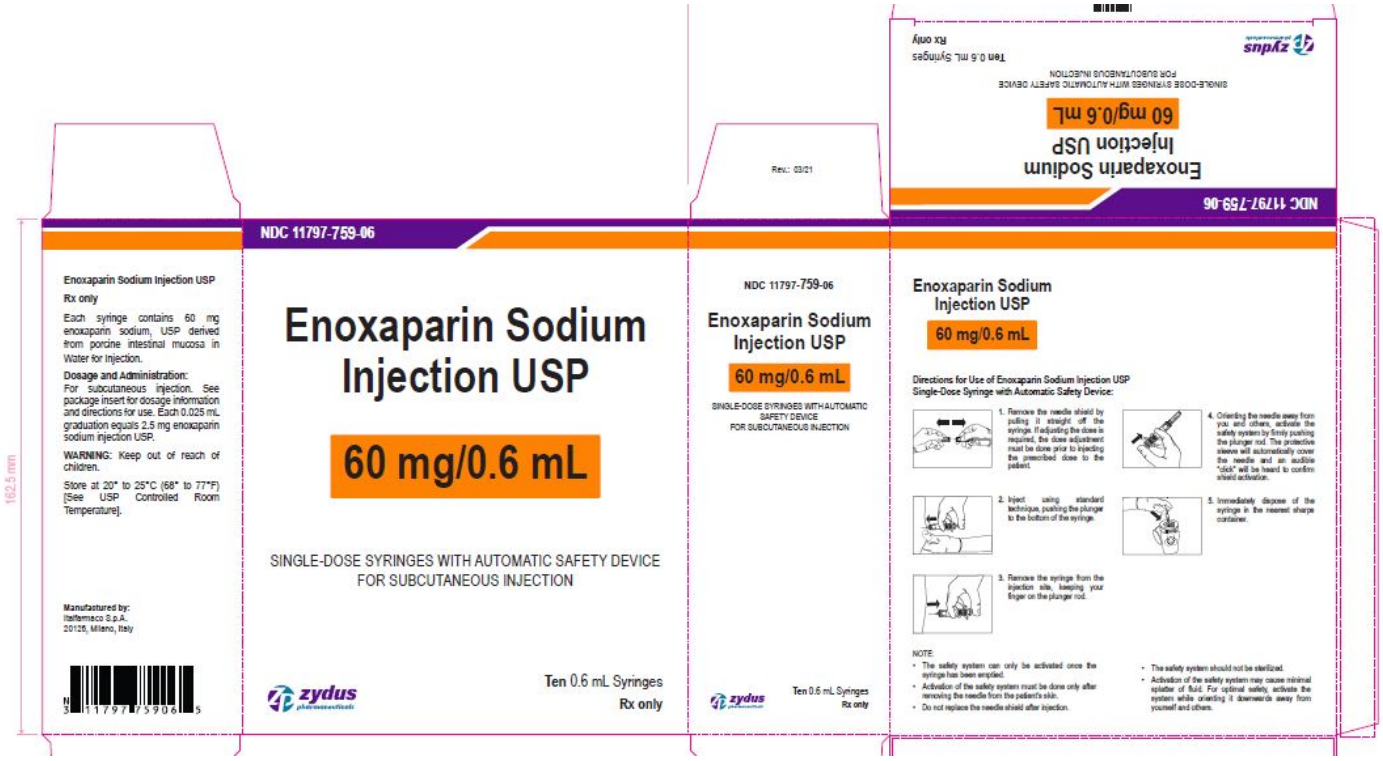
Enoxaparin Sodium Injection USP

60 mg/0.6 mL

SINGLE-DOSE SYRINGES WITH AUTOMATIC SAFETY DEVICE

FOR SUBCUTANEOUS INJECTION

Ten 0.6 mL Syringes



NDC **11797-760-06**

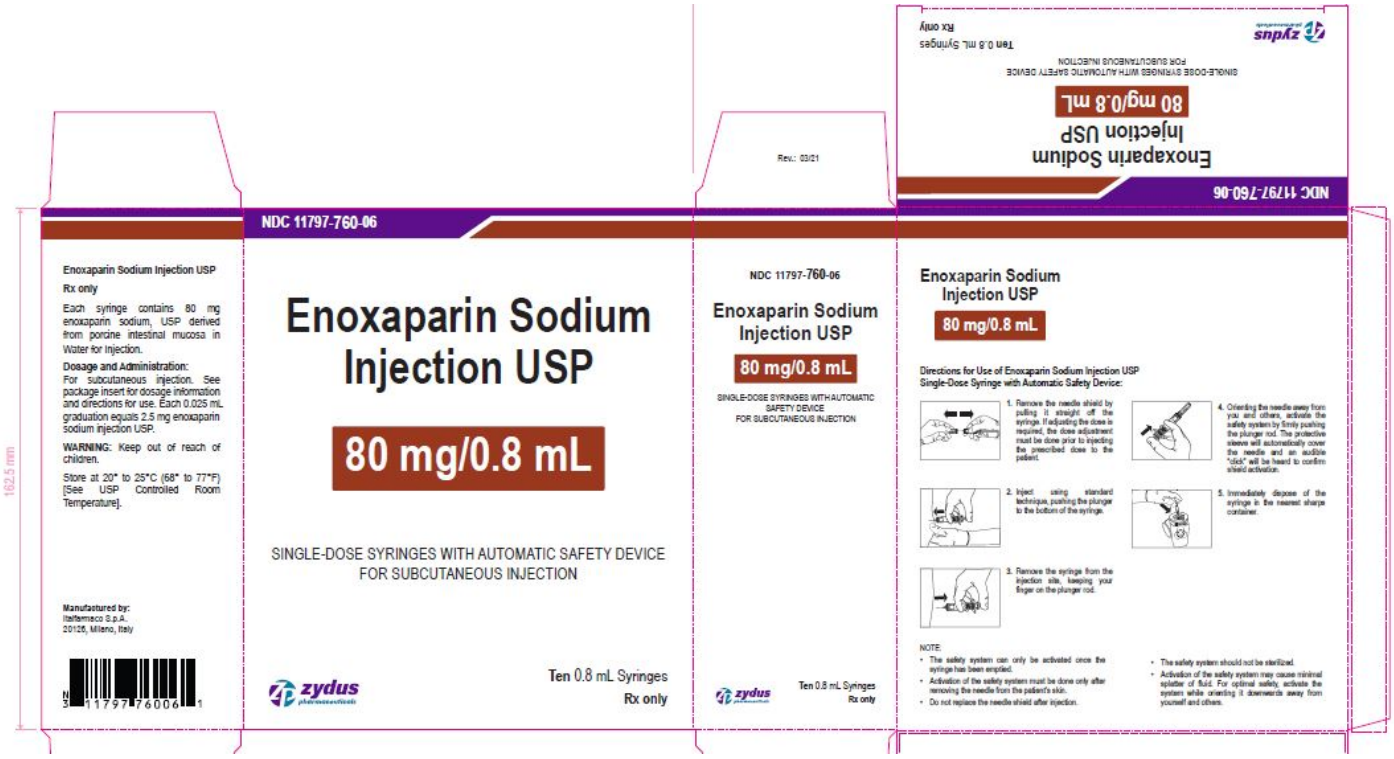
Enoxaparin Sodium Injection USP

80 mg/0.8 mL

SINGLE-DOSE SYRINGES WITH AUTOMATIC SAFETY DEVICE

FOR SUBCUTANEOUS INJECTION

Ten 0.8 mL Syringes



NDC 11797-761-06

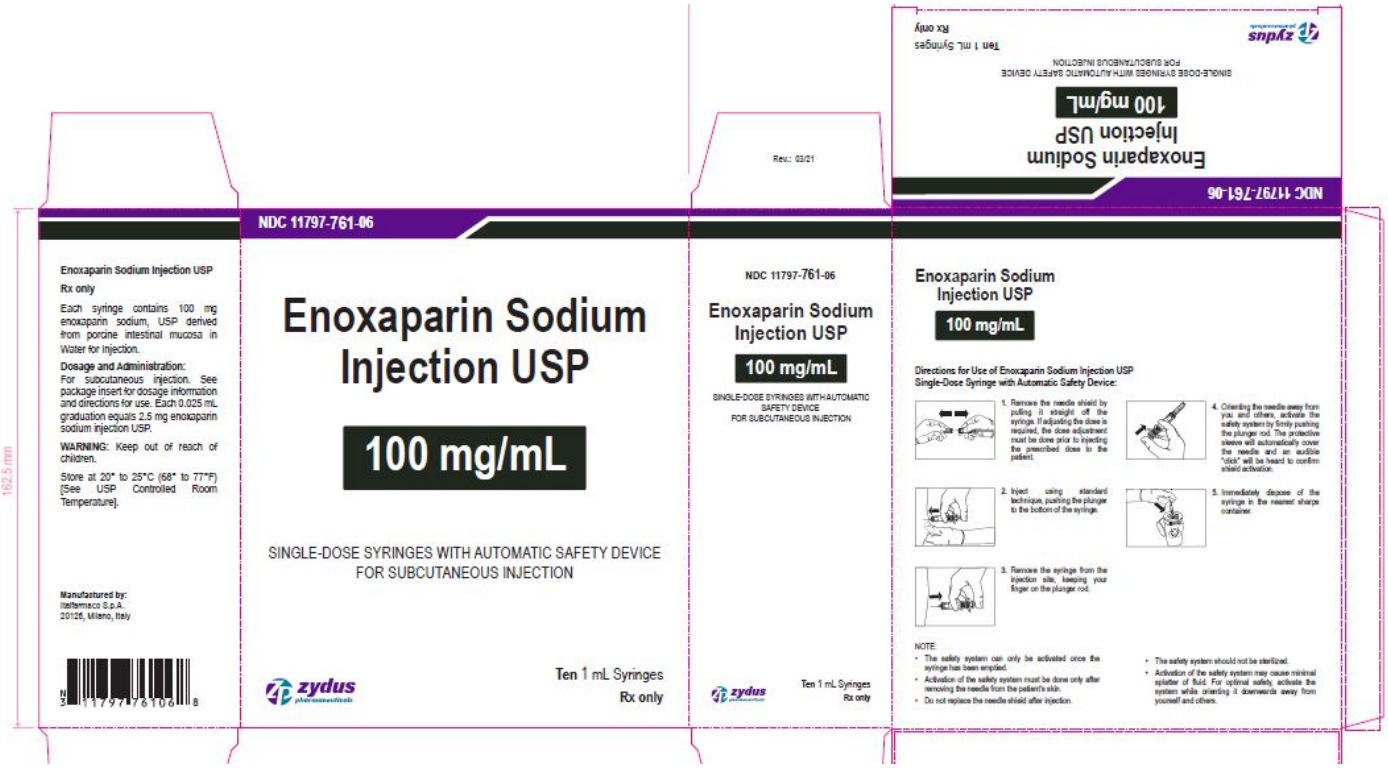
Enoxaparin Sodium Injection USP

100 mg/1 mL

SINGLE-DOSE SYRINGES WITH AUTOMATIC SAFETY DEVICE

FOR SUBCUTANEOUS INJECTION

Ten 1 mL Syringes



NDC **11797-762-06**

Enoxaparin Sodium Injection USP

120 mg/0.8 mL

SINGLE-DOSE SYRINGES WITH AUTOMATIC SAFETY DEVICE

FOR SUBCUTANEOUS INJECTION

Ten 0.8 mL Syringes

NDC 11797-763-06

Enoxaparin Sodium Injection USP

150 mg/1 mL

SINGLE-DOSE SYRINGES WITH AUTOMATIC SAFETY DEVICE

FOR SUBCUTANEOUS INJECTION

Ten 1 mL Syringes

ENOXAPARIN SODIUM

enoxaparin sodium injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11797-757
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ENOXAPARIN SODIUM (UNII: 8NZ41MIK1O) (ENOXAPARIN - UNII:E47C0NF7LV)	ENOXAPARIN SODIUM	30 mg in 0.3 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11797-757-06	10 in 1 CARTON	04/01/2021	
1	NDC:11797-757-02	0.3 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076726	04/01/2021	

ENOXAPARIN SODIUM

enoxaparin sodium injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11797-758
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENOXAPARIN SODIUM (UNII: 8NZ41MIK1O) (ENOXAPARIN - UNII:E47C0NF7LV)	ENOXAPARIN SODIUM	40 mg in 0.4 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11797-758-06	10 in 1 CARTON	04/01/2021	
1	NDC:11797-758-02	0.4 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076726	04/01/2021	

ENOXAPARIN SODIUM

enoxaparin sodium injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11797-759
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ENOXAPARIN SODIUM (UNII: 8NZ41MIK1O) (ENOXAPARIN - UNII:E47C0NF7LV)	ENOXAPARIN SODIUM	60 mg in 0.6 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11797-759-06	10 in 1 CARTON	04/01/2021	
1	NDC:11797-759-02	0.6 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076726	04/01/2021	

ENOXAPARIN SODIUM

enoxaparin sodium injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11797-760
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ENOXAPARIN SODIUM (UNII: 8NZ41MIK1O) (ENOXAPARIN - UNII:E47C0NF7LV)	ENOXAPARIN SODIUM	80 mg in 0.8 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11797-760-06	10 in 1 CARTON	04/01/2021	
1	NDC:11797-760-02	0.8 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076726	04/01/2021	

ENOXAPARIN SODIUM

enoxaparin sodium injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11797-761
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ENOXAPARIN SODIUM (UNII: 8NZ41MIK1O) (ENOXAPARIN - UNII:E47C0NF7LV)	ENOXAPARIN SODIUM	100 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11797-761-06	10 in 1 CARTON	04/01/2021	
1	NDC:11797-761-02	1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076726	04/01/2021	

ENOXAPARIN SODIUM

enoxaparin sodium injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11797-762
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ENOXAPARIN SODIUM (UNII: 8NZ41MIK1O) (ENOXAPARIN - UNII:E47C0NF7LV)	ENOXAPARIN SODIUM	120 mg in 0.8 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11797-762-06	10 in 1 CARTON	04/01/2021	
1	NDC:11797-762-02	0.8 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076726	04/01/2021	

ENOXAPARIN SODIUM

enoxaparin sodium injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11797-763
Route of Administration	INTRAVENOUS, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ENOXAPARIN SODIUM (UNII: 8NZ41MIK1O) (ENOXAPARIN - UNII:E47C0NF7LV)	ENOXAPARIN SODIUM	150 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11797-763-06	10 in 1 CARTON	04/01/2021	
1	NDC:11797-763-02	1 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076726	04/01/2021	

Labeler - Italfarmaco SpA (428179329)

Establishment

Name	Address	ID/FEI	Business Operations
Italfarmaco SpA		428179329	MANUFACTURE(11797-757, 11797-758, 11797-759, 11797-760, 11797-761, 11797-762, 11797-763)

Revised: 11/2022 Italfarmaco SpA