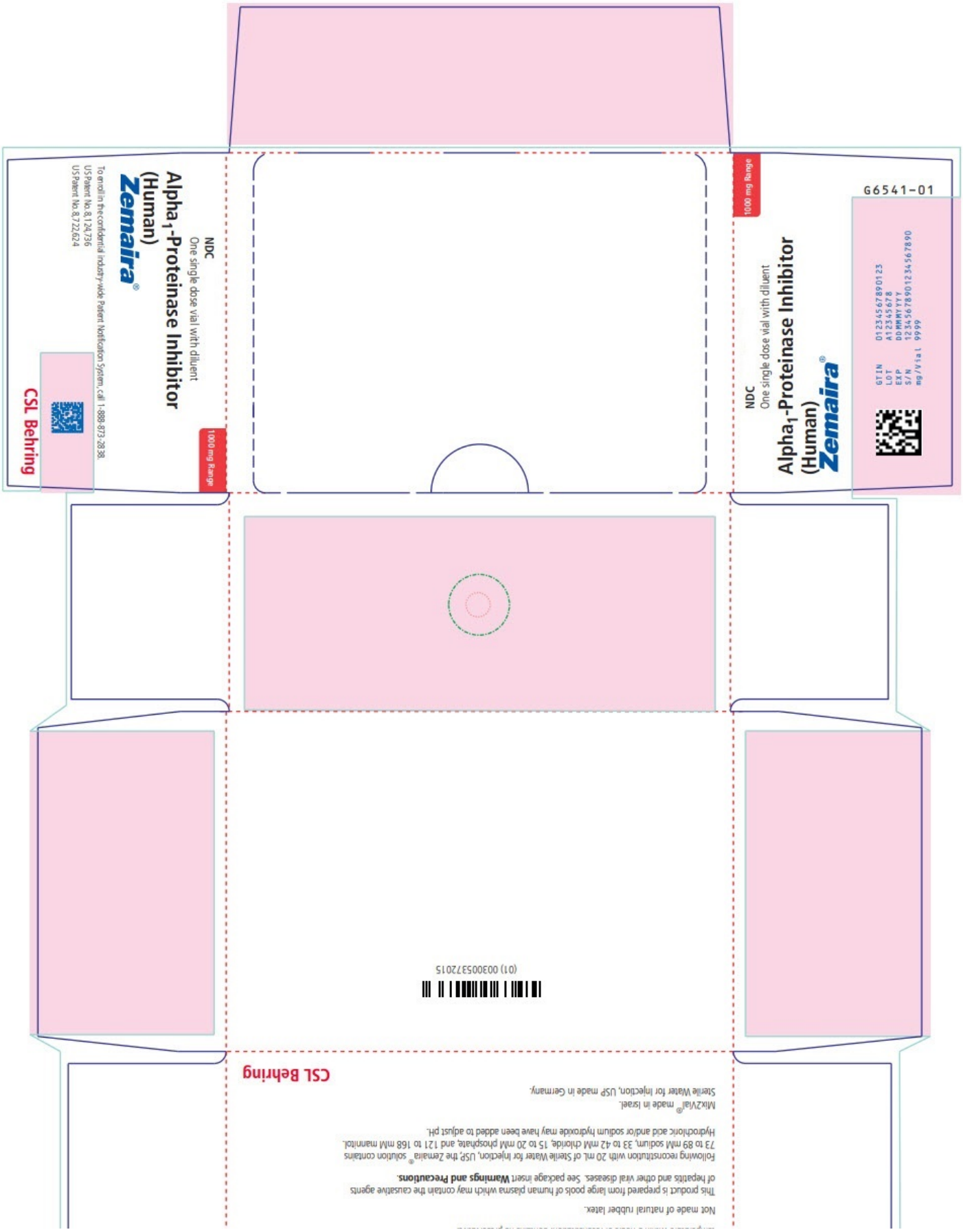
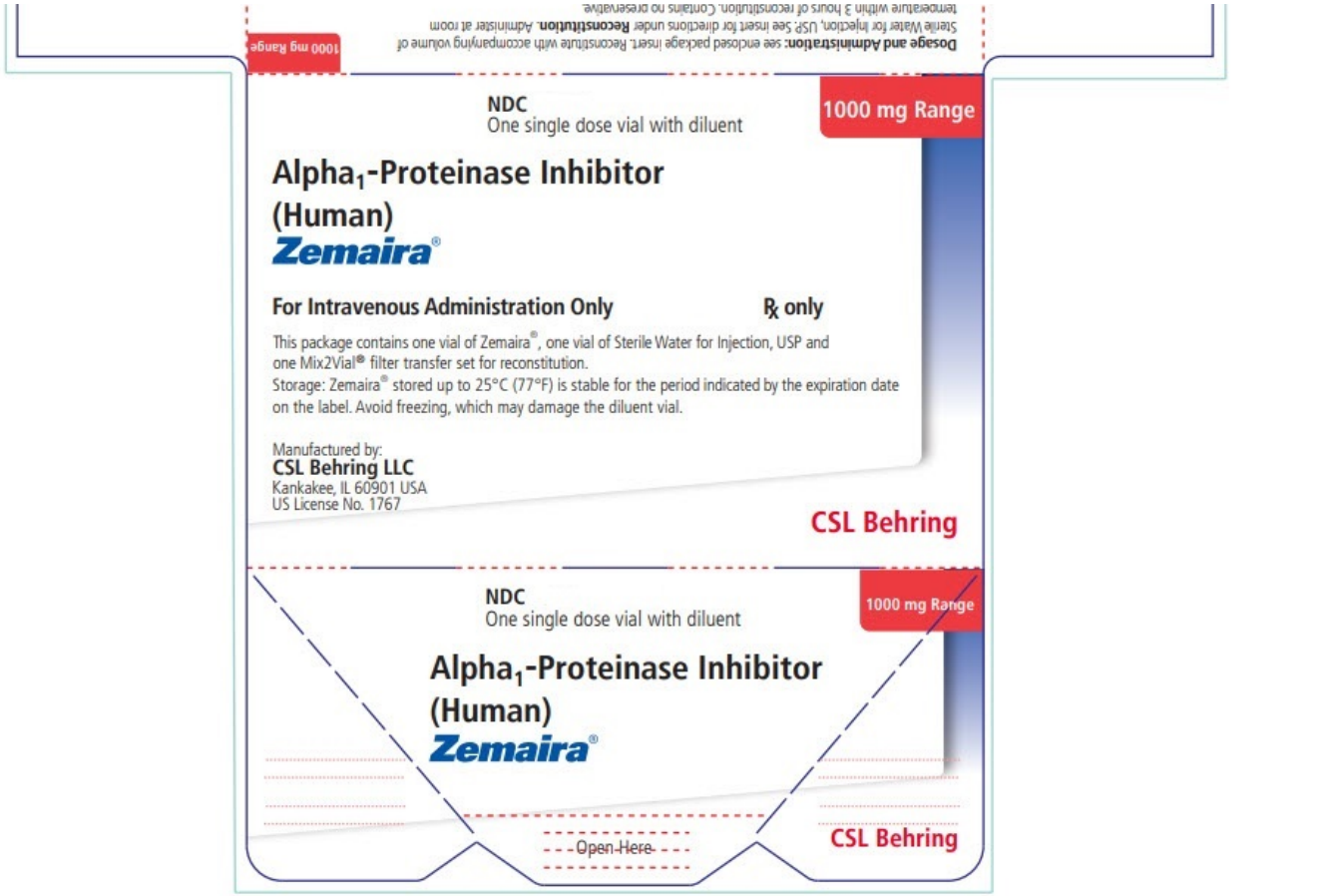
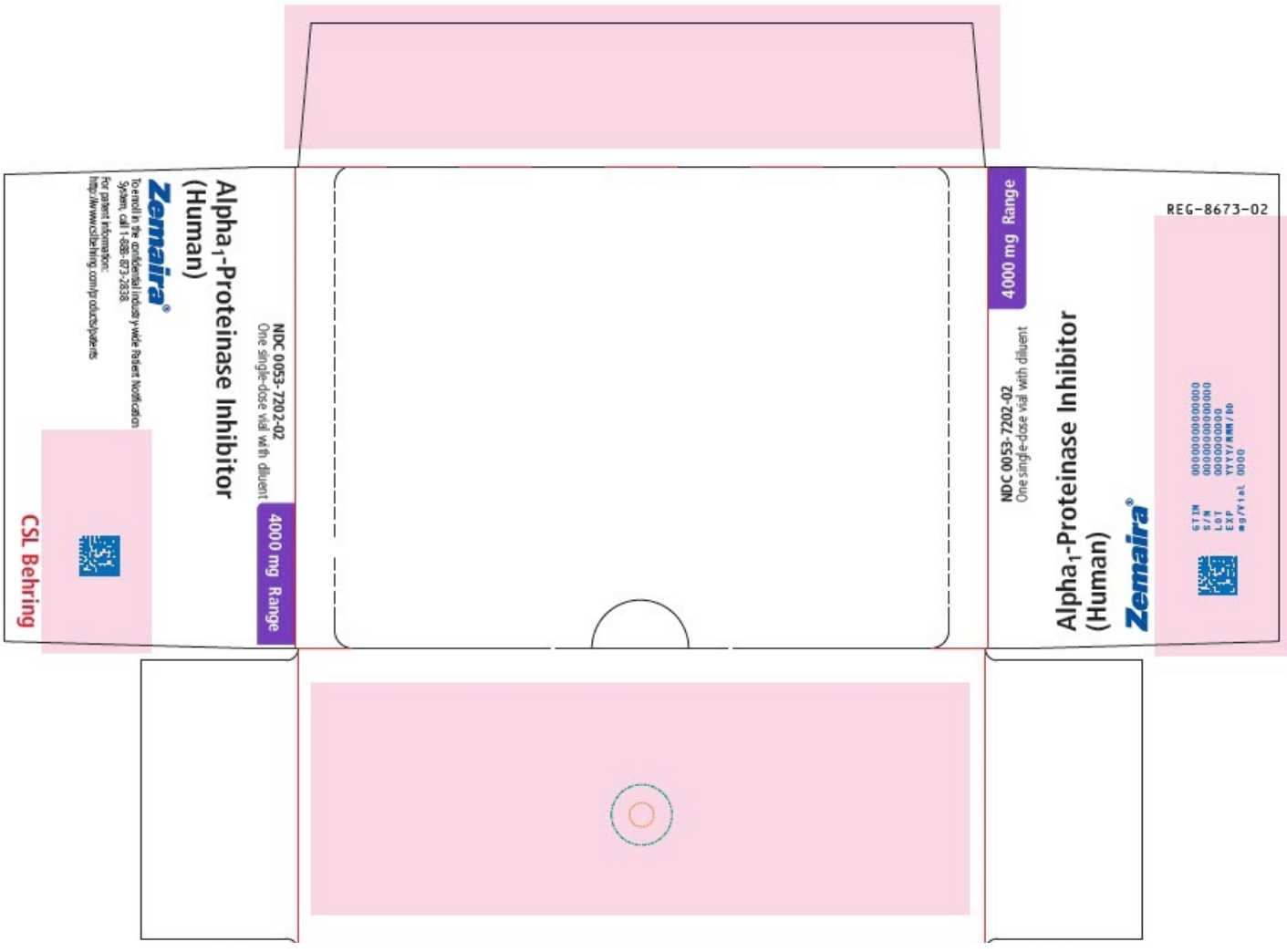
ZEMAIRA- alpha-1-proteinase inhibitor human kit
Fisher Clinical Services Inc.




Dosage and Administration: see enclosed package insert. Reconstitute with accompanying volume of Sterile Water for Injection, USP. See insert for directions under Reconstitution. Administer at room temperature within 3 hours of reconstitution. Contains no preservative.
1000 mg Range
NDC
One single dose vial with diluent
1000 mg Range
Alpha1-Proteinase Inhibitor (Human)
Zemaira®
For Intravenous Administration Only
℞ only
This package contains one vial of Zemaira®, one vial of Sterile Water for Injection, USP and one Mix2Vial® filter transfer set for reconstitution.
Storage: Zemaira® stored up to 25°C (77°F) is stable for the period indicated by the expiration date on the label. Avoid freezing, which may damage the diluent vial.
Manufactured by:
CSL Behring LLC
Kankakee, IL 60901 USA
US License No. 1767
CSL Behring
NDC
One single dose vial with diluent
1000 mg Range
Alpha1-Proteinase Inhibitor (Human)
Zemaira®
Open Here
CSL Behring


Zemaira®
To enroll in the confidential Industry-wide Patient Notification System, call 1-888-872-2838.
For patient information:
http://www.cslbehring.com/products/patients
Alpha1-Proteinase Inhibitor (Human)
NDC 0053-7202-02
One single-dose vial with diluent
4000 mg Range
CSL Behring
4000 mg Range
NDC 0053-7202-02
One single-dose vial with diluent
Alpha1-Proteinase Inhibitor (Human)
Zemaira®
REG-8673-02
GTIN 00000000000000
S/N 00000000000000
LOT 00000000000
EXP YY/MM/DD
(01)(17)(10)0000

CSL Behring

Mix2Vial® made in Israel.

Following reconstitution with 76 mL of Sterile Water for Injection, USP, the Zemaira® solution contains 73 to 89 mM sodium, 30 to 39 mM chloride, 15 to 20 mM phosphate, and 121 to 168 mM mannitol. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH.

This product is prepared from large pools of human plasma which may contain the causative agents of hepatitis and other viral diseases. See package insert **Warnings and Precautions**.

Not made of natural rubber latex.

Contains no preservative.

Administer at room temperature within 3 hours of reconstitution.

See insert for directions under **Reconstitution**.

Reconstitute with accompanying volume of Sterile Water for Injection, USP.

Dosage and Administration: see enclosed package insert.

4000 mg Range

4000 mg Range

NDC 0053-7202-02
One single-dose vial with diluent

Alpha$_1$-Proteinase Inhibitor (Human)

Zemaira®

For Intravenous Administration Only **℞ only**

This package contains one single-dose vial of Zemaira®, one vial of Sterile Water for Injection, USP and one Mix2Vial® filter transfer set for reconstitution.

Storage: Zemaira® stored up to 25°C (77°F) is stable for the period indicated by the expiration date on the label. Avoid freezing, which may damage the diluent vial.

Manufactured by:
CSL Behring LLC
Kankakee, IL 60901 USA
US License No. 1767

CSL Behring

4000 mg Range

NDC 0053-7202-02
One single-dose vial with diluent

Alpha$_1$-Proteinase Inhibitor (Human)

Zemaira®

Open Here

CSL Behring

NDC 0053-7203-02
One single-dose vial with diluent

5000 mg Range

Alpha$_1$-Proteinase Inhibitor (Human)

Zemaira®

Dosage and Administration: see enclosed package insert.

Reconstitute with accompanying volume of Sterile Water for Injection, USP.
See Insert for directions under **Reconstitution**.

Administer at room temperature within 3 hours of reconstitution.

Contains no preservative.

Not made of natural rubber latex.

This product is prepared from large pools of human plasma which may contain the causative agents of hepatitis and other viral diseases. See package insert **Warnings and Precautions**.

Following reconstitution with 95 mL of Sterile Water for Injection, USP, the Zemaira® solution contains 73 to 89 mM sodium, 30 to 39 mM chloride, 15 to 20 mM phosphate, and 121 to 168 mM mannitol. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH.

MIKZVAI® made in Israel.

CSL Behring

0 300537 203029

5000 mg Range

NDC 0053-7203-02
One single-dose vial with diluent

Alpha$_1$-Proteinase Inhibitor (Human)

Zemaira®

REG-8675-03

GTIN 00000000000000
S/N 00000000000
LOT 00000000
EXP YYYY/MM/DD
Rx Only 0000

5000 mg Range

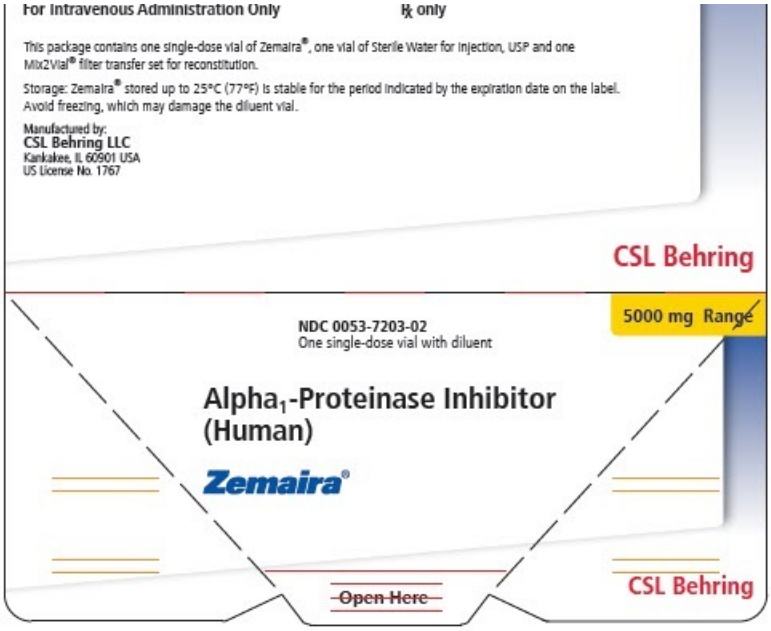
NDC 0053-7203-02
One single-dose vial with diluent

Alpha$_1$-Proteinase Inhibitor (Human)

Zemaira®

CSL Behring

To enroll in the confidential industry-wide Patient Notification System, call 1-888-873-2838.
For patient information:
http://www.cslbehring.com/products/patients



ZEMAIRA

alpha-1-proteinase inhibitor human kit kit

Product Information			
Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:57516-113

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57516-113-02	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 VIAL, SINGLE-DOSE	95 mL
Part 2	1 VIAL, SINGLE-DOSE	95 mL

Part 1 of 2

ALPHA-1-PROTEINASE INHIBITOR HUMAN

alpha-1-proteinase inhibitor human injection, powder, lyophilized, for solution

Product Information	
Item Code (Source)	NDC:57516-114
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
.ALPHA.1-PROTEINASE INHIBITOR HUMAN (UNII: F43I396OIS) (.ALPHA.1-PROTEINASE INHIBITOR HUMAN - UNII:F43I396OIS)	.ALPHA.1-PROTEINASE INHIBITOR HUMAN	5000 mg in 95 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57516-114-01	95 mL in 1 VIAL, SINGLE-DOSE; Type 6: Drug/Biologic Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	07/31/2023	

Part 2 of 2

DILUENT

water injection injection

Product Information	
Item Code (Source)	NDC:57516-115
Route of Administration	INTRAVENOUS

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57516-	95 mL in 1 VIAL, SINGLE-DOSE; Type 6: Drug/Biologic		

1	115-20	Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	04/24/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	07/31/2023	

ZEMAIRA

alpha-1-proteinase inhibitor human kit kit

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:57516-110

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57516-110-02	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, SINGLE-DOSE	76 mL
Part 2	1 VIAL, SINGLE-DOSE	76 mL

Part 1 of 2

ALPHA-1-PROTEINASE INHIBITOR HUMAN

alpha-1-proteinase inhibitor human injection, powder, lyophilized, for solution

Product Information

Item Code (Source)	NDC:57516-111
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.ALPHA.1-PROTEINASE INHIBITOR HUMAN (UNII: F43I396OIS) (.ALPHA.1-PROTEINASE INHIBITOR HUMAN - UNII:F43I396OIS)	.ALPHA.1-PROTEINASE INHIBITOR HUMAN	4000 mg in 76 mL

Inactive Ingredients

Ingredient Name	Strength
MANNITOL (UNII: 3OWL53L36A)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57516-111-01	76 mL in 1 VIAL, SINGLE-DOSE; Type 6: Drug/Biologic Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	07/31/2023	

Part 2 of 2

DILUENT

water injection injection

Product Information

Item Code (Source)	NDC:57516-112
Route of Administration	INTRAVENOUS

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57516-112-20	76 mL in 1 VIAL, SINGLE-DOSE; Type 6: Drug/Biologic Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	07/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	07/31/2023	

ZEMAIRA

alpha-1-proteinase inhibitor human kit kit

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:57516-101

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57516-101-02	1 in 1 CARTON		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 VIAL, SINGLE-DOSE	20 mL
Part 2	1 VIAL, SINGLE-DOSE	20 mL

Part 1 of 2

ALPHA-1-PROTEINASE INHIBITOR HUMAN

alpha-1-proteinase inhibitor human injection, powder, lyophilized, for solution

Product Information

Item Code (Source)	NDC:57516-102
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

.ALPHA.1-PROTEINASE INHIBITOR HUMAN (UNII: F43I396OIS) (.ALPHA.1-PROTEINASE INHIBITOR HUMAN - UNII:F43I396OIS)	.ALPHA.1-PROTEINASE INHIBITOR HUMAN	1000 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	525 mg in 20 mL
SODIUM PHOSPHATE (UNII: SE337SVY37)	47 mg in 20 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	44 mg in 20 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57516-102-01	20 mL in 1 VIAL, SINGLE-DOSE; Type 6: Drug/Biologic Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	02/22/2022	

Part 2 of 2

DILUENT

water injection injection

Product Information

Item Code (Source)	NDC:57516-103
Route of Administration	INTRAVENOUS

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57516-103-20	20 mL in 1 VIAL, SINGLE-DOSE; Type 6: Drug/Biologic Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	02/22/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125078	02/22/2022	

Labeler - Fisher Clinical Services Inc. (199879800)

Registrant - Fisher Clinical Services (079957165)

Establishment

Name	Address	ID/FEI	Business Operations
Fisher Clinical Services Inc.		199879800	manufacture(57516-101, 57516-110, 57516-113) , pack(57516-101, 57516-110, 57516-113) , label(57516-110, 57516-101, 57516-113)

Revised: 3/2025 Fisher Clinical Services Inc.