SODIUM CITRATE BLOOD-PACK UNITS, (PL 146 PLASTIC) - anticoagulant sodium citrate solution solution Fenwal. Inc.

Anticoagulant Sodium Citrate Solution USP

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A standalone direction insert does not exist for this product.

PACKAGE/LABEL DISPLAY PANEL

Fenwal™

Anticoagulant Sodium Citrate Solution USP

Rx only

CODE 4B7867Q

NDC 0942-9505-10

250 mL

EACH 100 mL CONTAINS 4 g SODIUM CITRATE (DIHYDRATE) USP pH ADJUSTED WITH CITRIC ACID STERILE NONPYROGENIC

FOR USE WITH CYTAPHERESIS DEVICE ONLY

NOT FOR DIRECT INTRAVENOUS INFUSION

SINGLE USE CONTAINER

DISCARD UNUSED PORTION

DO NOT USE UNLESS SOLUTION IS CLEAR AND NO LEAKS ARE DETECTED AFTER REMOVING OVERWRAP CHECK FOR MINUTE LEAKS BY SQUEEZING INNER BAG FIRMLY

IF LEAKS ARE FOUND DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED **CAUTION**- DO NOT REMOVE UNIT FROM OVERWRAP UNTIL READY FOR USE THE OVERWRAP IS A MOISTURE BARRIER THE INNER BAG MAINTAINS THE STERILITY OF THE PRODUCT STORE AT CONTROLLED ROOM TEMPERATURE

PL 146 PLASTIC

MANUFACTURED BY:

BAXTER HEALTHCARE CORPORATION

DEERFIELD, IL 60015 USA

MANUFACTURED FOR:



MADE IN USA

07-25-02-996 REV: C

3	
Fenwal	
Anticoagulant	FO
Sodium Citrate	50
Solution USP Rx only	
CODE 4B7867Q NDC 0942-9505-10	
250 mL EACH 100 mL CONTAINS 4 g	100
SODIUM CITRATE (DIHYDRATE) USP	100
ph Adjusted with citric acid	
STERILE NONPYROGENIC	
FOR USE WITH CYTAPHERESIS DEVICE ONLY	
NOT FOR DIRECT INTRAVENOUS INFUSION	
SINGLE USE CONTAINER DISCARD UNUSED	150
PORTION DO NOT USE UNLESS SOLUTION IS CLEAR AND NO LEAKS ARE DETECTED.	
AFTER REMOVING OVERWRAP CHECK FOR	
MINUTE LEAKS BY SQUEEZING INNER BAG	
FIRMLY IF LEAKS ARE FOUND DISCARD	
SOLUTION AS STERILITY MAY BE IMPAIRED	
CAUTION - DO NOT REMOVE UNIT FROM	
OVERWRAP UNTIL READY FOR USE	200
THE OVERWRAP IS A MOISTURE BARRIER	200
THE INNER BAG MAINTAINS THE STERILITY	

MANUFACTURED BY:

BAXTER HEALTHCARE CORPORATION

OF THE PRODUCT STORE AT CONTROLLED ROOM TEMPERATURE

DEERFIELD, IL 60015 USA

MANUFACTURED FOR:

...

FENWAL, INC.

LAKE ZURICH, IL 60047 USA

MADE IN USA

07-25-02-996 REV: C

SODIUM CITRATE BLOOD-PACK UNITS, (PL 146 PLASTIC)

anticoagulant sodium citrate solution solution

PL 146 PLASTIC

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0942-9505
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Strength	Strength
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	4 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:0942-9505- 10	250 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN770923	03/01/2007	

Labeler - Fenwal, Inc. (794519020)

Registrant - Fenwal, Inc. (794519020)

Establishment				
Name	Address	ID/FEI	Business Operations	
Baxter Healthcare Corporation		059140764	MANUFACTURE(0942-9505)	

Revised: 2/2022 Fenwal, Inc.