

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

Fenwal, Inc.

PACKAGE/LABEL DISPLAY PANEL

**CAUTION—DO NOT REMOVE UNIT FROM OVERWRAP UNTIL READY FOR USE
THE OVERWRAP IS A MOISTURE BARRIER
THE INNER BAG MAINTAINS STERILITY OF THE PRODUCT
STORE AT CONTROLLED ROOM TEMPERATURE.**

CODE 4B7889Q

NDC 0942-9504-10

500 mL

Fenwal™

Anticoagulant Sodium Citrate Solution USP

Rx only

**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

MANUFACTURED BY:

BAXTER HEALTHCARE CORPORATION

DEERFIELD, IL 60015 USA

MANUFACTURED FOR:

FENWAL, INC.

LAKE ZURICH, IL 60047 USA

MADE IN USA

07-25-58-000

PL 146 PLASTIC

LOT

EXP

1-

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-1

2-

**CODE 4B7889Q
NDC 0942-9504-10**

500 mL

-2



3-

Anticoagulant Sodium Citrate Solution USP

-3

Rx only

4-

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STERILE NONPYROGENIC**

-4

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anticoagulant sodium citrate solution solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0942-9504
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Page 1 of 1

Ingredient Name		Basis of 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)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0942-9504-10	500 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
Fenwal International, Inc.		091164590	MANUFACTURE(0942-9504)

Revised: 10/2014

Fenwal, Inc.