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

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Anticoagulant Sodium Citrate Solution USP

#### **Anticoagulant Sodium Citrate Solution USP**

A standalone direction insert does not exist for this product.

#### 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 4B78890** 

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

STFRII F

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.

#### **MADE IN USA**

07-25-58-000

#### **PL 146 PLASTIC**

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READY FOR USE THE INNER BAG MAI	EMOVE UNIT FROM OVERWE HE OVERWRAP IS A MOISTU INTAINS STERILITY OF THE I LLED ROOM TEMPERATURE.	RE BARRIER PRODUCT
CODE 4B7889Q NDC 0942-9504-10		500 mL
Fenwal <sup>™</sup>		
Anticoagu	ulant Sodium	
STATE OF STA	lution USP	
Rx only		
EACH 100 mL CONT (DIHYDRATE) USP	AINS 4 g SODIUM CITRATE pH ADJUSTED WITH CITRIC	ACID
STERILE NONPYRO		
	APHERESIS DEVICE ONLY TRAVENOUS INFUSION	
	INER DISCARD UNUSED P	ORTION
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BY SQUEEZING INN	OVERWRAP CHECK FOR MII ER BAG FIRMLY IF LEAKS NAS STERILITY MAY BE IMF	ARE FOUND
MANUFACTURED BY: BAXTER HEALTHCARE CO DEERFIELD, IL 60015 USA	ORPORATION	
MANUFACTURED FOR:	DI	146 PLASTIC
FENWAL, INC. LAKE ZURICH, IL 60047 USA		140 PLASTIC
MADE IN LISA		

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

anticoagulant sodium citrate solution solution

07-25-58-000

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

Active Ingredient/Active Moiety			
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)		

P	ackaging			
#	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	<b>Business Operations</b>	
Baxter Healthcare Corporation		059140764	MANUFACTURE(0942-9504)	

Revised: 2/2022 Fenwal, Inc.