ANTICOAGULANT SODIUM CITRATE- trisodium citrate dihydrate solution
Baxter Healthcare Corporation

ANTICOAGULANT SODIUM CITRATE 4% w/v SOLUTION USP

INDICATIONS AND USAGE

Anticoagulant Sodium Citrate 4% w/v Solution, USP is intended for use only with automated apheresis devices.

ADMINISTRATION

The pouch is a moisture barrier. Do not remove from pouch until ready to use. Do not use unless solution is clear and no leaks detected. Do not use unless port protector is in place.

DOSAGE FORMS AND STRENGTHS

Anticoagulant Sodium Citrate 4% w/v Solution, USP in the 250 mL single dose container is a sterile solution that contains 4g Sodium Citrate Dihydrate, USP per 100 mL, pH adjusted with citric acid.

PRECAUTIONS

Not for direct intravenous infusion.

HOW SUPPLIED

Anticoagulant Sodium Citrate 4% w/v Solution, USP is a clear solution supplied in sterile and nonpyrogenic PVC bags per carton.

Storage and Handling

Store at room temperature (25C/77F). Avoid excessive heat. Protect from freezing.

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

LOT EXP

2B7867
NDC 0338-9669-01

Anticoagulant
Sodium Citrate
4% w/v
Solution USP **Rx only**

250 mL EACH 100 mL CONTAINS 4 g SODIUM CITRATE (DIHYDRATE) USP
pH ADJUSTED WITH CITRIC ACID
STERILE NONPYROGENIC
INTENDED FOR USE ONLY WITH AUTOMATED APHERESIS DEVICES
CAUTION — NOT FOR DIRECT INTRAVENOUS INFUSION THE POUCH IS A MOISTURE BARRIER DO NOT USE UNLESS SOLUTION IS CLEAR SQUEEZE AND INSPECT INNER BAG WHICH MAINTAINS PRODUCT STERILITY DISCARD IF LEAKS ARE FOUND SINGLE USE CONTAINER DISCARD UNUSED PORTION DIRECTIONS FOR USE ARE CONTAINED IN THE OWNERS OPERATING AND MAINTENANCE MANUAL OF THE APHERESIS MACHINE TO BE USED
RECOMMENDED STORAGE
ROOM TEMPERATURE (25C/77F) AVOID EXCESSIVE HEAT PROTECT FROM FREEZING.
FOR PRODUCT INFORMATION 1-800-933-0303
BAXTER IS A TRADEMARK OF BAXTER INTERNATIONAL

Baxter
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA

MADE IN USA 07-25-00-4675

LOT

EXP

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ANTICOAGULANT SODIUM CITRATE
trisodium citrate dihydrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0338-9669
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	40 mg in 1 mL

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

Packaging				
			Marketing Start	**Marketing End**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-9669-01	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	BN980123	04/02/2024	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		059140764	MANUFACTURE(0338-9669)

Revised: 4/2024 Baxter Healthcare Corporation