SODIUM CITRATE W/V ANTICOAGULANT- trisodium citrate dihydrate injection, solution
Terumo BCT, Ltd

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP safely and effectively. See full prescribing information for SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP.

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP

Sterile Fluid
Polyolefin Bag

Initial U.S. Approval: 1978

INDICATIONS AND USAGE

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP is intended for use only for the anticoagulation of whole blood as part of automated apheresis procedures. (1)

DOSAGE AND ADMINISTRATION

- SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP is added to tubing sets during apheresis procedures. (2)
- SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP may only be used with apheresis devices. For instructions on the use of the solution see the apheresis device operator's manual. (2.1)
- Follow the directions for connecting the SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP bag to the apheresis system. (2.2)

DOSAGE FORMS AND STRENGTHS

- 250 mL sterile fluid in a polyolefin bag. (3)

CONTRAINDICATIONS

- DO NOT INFUSE SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP DIRECTLY TO THE DONOR. (4)

WARNINGS AND PRECAUTIONS

- Verify that the SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP has been securely attached to the anticoagulant (AC) line on the system tubing set. Use aseptic technique throughout all procedures to ensure donor safety and quality.
- Single-use container, do not reuse. Discard any unused or partially used product.
- Rx only (5)

ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the infusion and return of blood containing citrate anticoagulant. The recipient of the blood containing citrate should be monitored for the signs and symptoms of citrate toxicity. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Terumo BCT, Inc. at 1-877-339-4228 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

USE IN SPECIFIC POPULATIONS

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP has not been studied in controlled clinical trials with specific populations. (7)

Revised: 12/2019

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP is intended for use only for the anticoagulation of whole blood as part of automated apheresis procedures. *[See Dosage and Administration (2).]*

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP is added to tubing sets during apheresis procedures. The solution bag is connected to the tubing set in an apheresis collection. The recommended dose is determined by the apheresis device and metered into the tubing set by the apheresis device. It is not intended for direct intravenous infusion.

For instructions on the use of the solution with the apheresis device and tubing set, see the device operator's manual.

2.2 Administration

- Ensure solution is the SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP and is within the expiration date.
- Inspect the bag. Do not use if the container is damaged, leaking or if there is any visible sign of deterioration.
- Use only if solution is clear and free of particulate matter.
- Protect from sharp objects.

Directions for connecting the* SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP *bag to the apheresis device.

At the prompt to connect anticoagulant to the apheresis device tubing set:

1. Remove the overwrap by pulling down at the notch, and remove the SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP bag.
2. Before use, perform the following checks *[see Warnings and Precautions (5)]*:
   - Check for leaks by gently squeezing the bag. If leaks are found, discard the bag.
   - Ensure that the solution is the SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP and is within the expiration date.

- Inspect the solution in good light. Bags showing cloudiness, haze, or particulate matter should not be used.

3. Remove the protective cap from the port on the bag.
4. Connect the bag to the apheresis device tubing set using aseptic technique and hang the solution.
5. Proceed according to the apheresis device operator's manual.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

3 DOSAGE FORMS AND STRENGTHS

250 mL SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP is a sterile solution in a polyolefin bag. Each 100 mL contains: Sodium Citrate (dihydrate) 4.0 g; Water for Injection to 100 mL, (pH adjusted with citric acid). Approximate millimoles of Sodium Citrate: 13.8.

4 CONTRAINDICATIONS

DO NOT INFUSE SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP DIRECTLY TO THE DONOR.

5 WARNINGS AND PRECAUTIONS

- Verify that the SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP has been securely attached to the anticoagulant (AC) line on the system tubing set. Use aseptic technique throughout all procedures to ensure donor safety and quality.
- Single-use container. Do not reuse. Discard any unused or partially used product.
- Rx only.

6 ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the infusion of blood products to patients and return of blood containing citrate anticoagulant to donors. The recipient of the blood containing citrate should be monitored for the signs and symptoms of citrate toxicity. The signs and symptoms of citrate toxicity begin with paresthesia, a "tingling" sensation around the mouth or in the extremities, followed by severe reactions that are characterized by hypotension and possible cardiac arrhythmia. Citrate toxicity may occur more frequently in patients who are hypothermic, have impaired liver or renal function, or have low calcium levels because of an underlying disease.

8 USE IN SPECIFIC POPULATIONS

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP has not been adequately studied in controlled clinical trials with specific populations.

11 DESCRIPTION

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP is designed to be metered by an apheresis device in apheresis procedures, to prevent platelet activation and coagulation as blood moves throughout the extracorporeal unit (tubing set) in an apheresis procedure.

The solution is sterile and non-pyrogenic, and it contains no bacteriostatic or antimicrobial agents. Sterilized with steam.

The formulas of the active ingredients are provided in Table 1.

Table 1: Active Ingredients

Ingredients	Molecular Formula	Molecular Weight
Sodium Citrate Dihydrate	$C_6H_9Na_3O_9$	294.10
Water for Injection	H_2O	18.00

Each 100 mL of SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP contains: Sodium Citrate (dihydrate) 4.0 g; and Water for Injection to 100 mL (pH adjusted with citric acid). Approximate millimoles of sodium citrate: 13.8.

The polyolefin bag is not made with natural rubber latex.

The bag contains materials that have been tested to demonstrate the suitability of the container for storing pharmaceutical solutions. The bag is nontoxic and biologically inert. The bag-solution unit is a closed system and is not dependent upon entry of external air during administration. The bag is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP acts as an extracorporeal anticoagulant by binding the free calcium in the blood. Calcium is a necessary co-factor to several steps in the clotting cascade. The following ingredients are key components of the solution:

- Citric acid for pH regulation
- Sodium Citrate anticoagulant

This solution has no pharmacological effect.

16 HOW SUPPLIED/STORAGE AND HANDLING

SODIUM CITRATE 4% W/V ANTICOAGULANT SOLUTION USP is a clear solution supplied in sterile and non-pyrogenic polyolefin bags. The bags are packaged 30 bags per case.

SIZE	CATALOG NUMBER	NDC NUMBER	
250 mL	40883	Bag:	14537-883-00
		Case:	14537-883-03

STORAGE

Up to 25 °C.

Protect from freezing.

Issued: **December 2019**

Manufactured by
Terumo BCT, Inc.
10811 W. Collins Ave.
Lakewood, CO 80215

PRINCIPAL DISPLAY PANEL - 250 mL Bag Carton Label

Sodium Citrate 4% w/v Anticoagulant Solution USP

Catalog # 40883
Polyolefin Bag
30 x 250 mL units

NDC 14537-883-03

Indications for use: For use only for the anticoagulation of whole blood as part of automated apheresis procedures. See apheresis device operator's manual for complete instructions. Read the package insert before application. The solution is sterile and non-pyrogenic, and it contains no bacteriostatic or antimicrobial agents. Sterilized with Steam.

Caution: Use only if solution is clear. Do not use if the container is damaged. Single use container. Discard any unused product.
Not for direct intravenous infusion. Rx Only.

Recommended storage: Up to 25 °C. Protect from freezing.

Each 100 mL contains:
Sodium Citrate Dihydrate
4.0 g
Water for Injection to
(pH adjusted with citric acid)
100 mL
Approximate Millimoles:
Sodium Citrate
13.8

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Lot
Expiry Date

Sodium Citrate 4% w/v Anticoagulant Solution USP

Catalog # 40883 Polyolefin Bag 30 x 250 mL units

NDC 14537-883-03

Indications for use: For use only for the anticoagulation of whole blood as part of automated apheresis procedures. See apheresis device operator's manual for complete instructions. Read the package insert before application. The solution is sterile and non-pyrogenic, and it contains no bacteriostatic or antimicrobial agents. Sterilized with Steam.

Caution: Use only if solution is clear. Do not use if the container is damaged. Single use container. Discard any unused product.
Not for direct intravenous infusion. Rx Only.

Recommended storage: Up to 25 °C. Protect from freezing.

Each 100 mL contains:

Sodium Citrate Dihydrate	4.0 g
Water for Injection to (pH adjusted with citric acid)	100 mL

Approximate Millimoles:

Sodium Citrate	13.8

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Lot Expiry Date

SODIUM CITRATE W/V ANTICOAGULANT

trisodium citrate dihydrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14537-883

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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14537-883-03	30 in 1 CARTON		
1	NDC:14537-883-00	250 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	BA125608	06/26/2018	

Labeler - Terumo BCT, Ltd (233649834)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo BCT, Ltd		233649834	MANUFACTURE(14537-883) , ANALYSIS(14537-883) , STERILIZE(14537-883) , LABEL(14537-883)

Revised: 1/2020 Terumo BCT, Ltd