ACD A- citric acid monohydrate, dextrose monohydrate, and trisodium citrate dihydrate injection, solution
Terumo BCT, Ltd.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A safely and effectively. See full prescribing information for ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A.

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A

Sterile Fluid
Polyolefin Bag

Initial U.S. Approval: 1987

INDICATIONS AND USAGE

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is an anticoagulant for blood collection for use only with apheresis devices. (1)

DOSAGE AND ADMINISTRATION

- ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is added to tubing sets during apheresis procedures. (2)
- ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A 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 ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A bag to the apheresis system. (2.2)

DOSAGE FORMS AND STRENGTHS

- 500 mL or 750 mL sterile fluid in polyolefin bag. (3)

CONTRAINDICATIONS

- DO NOT INFUSE ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A DIRECTLY TO THE PATIENTS. (4)

WARNINGS AND PRECAUTIONS

- Verify that the ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A 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. (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

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A has not been studied in controlled clinical trials with specific populations. (7)

Revised: 8/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is an anticoagulant for blood collection for use only with apheresis devices. *[See Dosage and Administration (2).]*

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is added to tubing sets during apheresis procedures. The solution 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 ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A 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* ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A *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 notch, and remove the ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A 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 ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A and is within the expiration date.
   - Inspect the solution in adequate 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. Break the frangible connector. When you break frangible connectors, bend them in both directions to ensure that you break them completely. Failure to do so may result in restricted flow.
6. 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 solution and container permit.

3 DOSAGE FORMS AND STRENGTHS

500 mL or 750 mL ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is a sterile solution in a polyolefin bag. Each 100 mL contains: (%w/v) Citric Acid, Monohydrate 0.8 g; Dextrose Monohydrate 2.45 g; Sodium Citrate Dihydrate 2.2 g; and Water for Injection.

4 CONTRAINDICATIONS

DO NOT INFUSE ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A DIRECTLY TO THE PATIENTS.

5 WARNINGS AND PRECAUTIONS

- Verify that the ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A 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.
- Do not reuse. Discard unused or partially used solution bags.

6 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. 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

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A has not been adequately studied in controlled clinical trials with specific populations.

11 DESCRIPTION

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A 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.

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

Table 1: Active Ingredients

Ingredients	Molecular Formula	Molecular Weight
(%w/v) Citric Acid, Monohydrate	$C_6H_8O_7$	192.12
Dextrose Monohydrate	$C_6H_{12}O_6 \cdot H_2O$	198.17
Sodium Citrate Dihydrate	$C_6H_9Na_3O_9$	294.10
Water for Injection	H_2O	18.00

Each 100 mL of ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A contains: (%w/v) Citric Acid, Monohydrate 0.8 g; Dextrose Monohydrate 2.45 g; Sodium Citrate Dihydrate 2.2 g; and Water for Injection.

The polyolefin bag is not made with natural rubber latex or PVC.

The bag is made from a multilayered film. It contains materials that have been tested to demonstrate the suitability of the container for storing pharmaceutical solutions. The solution contact layer is an elasticized polyolefin. 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

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A 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 anticoagulates
- Dextrose for isotonicity

This solution has no pharmacological effect.

16 HOW SUPPLIED/STORAGE AND HANDLING

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is a clear solution supplied in sterile and non-pyrogenic polyolefin bags. The 750 mL bags are packaged 12 bags per case. The 500 mL bags are packaged 18 bags per case.

SIZE	CATALOG NUMBER	NDC NUMBER
500 mL	40815	14537-815-50
750 mL	40817	14537-817-75

STORAGE

Store up to 25 °C [See USP Controlled Room Temperature].
Avoid excessive heat. Protect from freezing.

Issued: (August 2017)

Manufactured by
Terumo BCT, Inc.
Lakewood, CO 80215

PRINCIPAL DISPLAY PANEL - 750 mL Bag Label

Anticoagulant Citrate Dextrose Solution USP (ACD) Solution A

Catalog # 40817
Polyolefin Bag
750 mL

NDC 14537-817-75

Sterile. Non-pyrogenic. Sterilized with Steam.

Do not use unless the solution is clear and the container is intact.

Rx Only.

Single use container.

Read the package insert before application.

For use only with apheresis devices. See apheresis device operator's manual for complete instructions.

Caution: Not for direct intravenous infusion.

Recommended storage:
Store up to 25 °C. (See USP Controlled Room Temperature).
Avoid excessive heat.
Protect from freezing.

Each 100 mL contains:
Dextrose Monohydrate USP
2.45 g
Sodium Citrate Dihydrate USP
2.20 g
Citric Acid Monohydrate USP
0.80 g
In Water for Injection USP

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

777967-057
TERUMOBCT

Lot
Expiry Date

Anticoagulant Citrate Dextrose Solution USP (ACD) Solution A

Catalog # 40817 Polyolefin Bag 750 mL

NDC 14537-817-75

Sterile. Non-pyrogenic. Sterilized with Steam.

Do not use unless the solution is clear and the container is intact.

Rx Only.

Single use container.

Read the package insert before application.

For use only with apheresis devices. See apheresis device operator's manual for complete instructions.

Caution: Not for direct intravenous infusion.

Recommended storage:
Store up to 25 °C. (See USP Controlled Room Temperature).
Avoid excessive heat.
Protect from freezing.

Each 100 mL contains:

Dextrose Monohydrate USP	2.45 g
Sodium Citrate Dihydrate USP	2.20 g
Citric Acid Monohydrate USP	0.80 g
In Water for Injection USP	

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777967-057

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Lot

Expiry Date

PRINCIPAL DISPLAY PANEL - 500 mL Bag Label

Anticoagulant Citrate Dextrose Solution USP (ACD) Solution A

Catalog # 40815
Polyolefin Bag
500 mL

NDC 14537-815-50

Sterile. Non-pyrogenic. Sterilized with Steam.

Do not use unless the solution is clear and the container is intact.

Rx Only.

Single use container.

Read the package insert before application.

For use only with apheresis devices. See apheresis device operator's manual for complete instructions.

Caution: Not for direct intravenous infusion.

Recommended storage:
Store up to 25 °C. (See USP Controlled Room Temperature).
Avoid excessive heat.
Protect from freezing.

Each 100 mL contains:
Dextrose Monohydrate USP
2.45 g
Sodium Citrate Dihydrate USP
2.20 g
Citric Acid Monohydrate USP
0.80 g
In Water for Injection USP

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777967-540
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Lot
Expiry Date

Anticoagulant Citrate Dextrose Solution USP (ACD) Solution A

Catalog # 40815 Polyolefin Bag 500 mL

NDC 14537-815-50

Sterile. Non-pyrogenic. Sterilized with Steam.
Do not use unless the solution is clear and the container is intact.
Rx Only.
Single use container.
Read the package insert before application.
For use only with apheresis devices. See apheresis device operator's manual for complete instructions.
Caution: Not for direct intravenous infusion.

Recommended storage:
Store up to 25 °C. (See USP Controlled Room Temperature).
Avoid excessive heat.
Protect from freezing.

Each 100 mL contains:

Dextrose Monohydrate USP	2.45 g
Sodium Citrate Dihydrate USP	2.20 g
Citric Acid Monohydrate USP	0.80 g
In Water for Injection USP	

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777967-540

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Lot Expiry Date

ACD A

citric acid monohydrate, dextrose monohydrate, and trisodium citrate dihydrate injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14537-817
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Citric Acid Monohydrate (UNII: 2968PHW8QP) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	0.8 g in 100 mL
	Dextrose	2.45 g

Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	2.45 g in 100 mL
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	2.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14537-817-75	12 in 1 CARTON		
1		750 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	BA010228	02/25/2002	

ACD A

citric acid monohydrate, dextrose monohydrate, and trisodium citrate dihydrate injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14537-815
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	0.8 g in 100 mL
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	2.45 g in 100 mL
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	2.2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14537-815-50	18 in 1 CARTON		
1		500 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	BA010228	02/25/2002	

Labeler - Terumo BCT, Ltd. (233649834)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo BCT, Ltd.		233649834	MANUFACTURE(14537-817, 14537-815) , STERILIZE(14537-817, 14537-815) , ANALYSIS(14537-817, 14537-815) , LABEL(14537-817, 14537-815)

Revised: 1/2019 Terumo BCT, Ltd.