ANTICOAGULANT CITRATE DEXTROSE (ACD-A)- dextrose monohydrate, sodium citrate, unspecified form, and citric acid monohydrate 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 Container (solution bag)
Clear Overwrap

Initial U.S. Approval: 2012

INDICATIONS AND USAGE

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is an anticoagulant intended for use only with devices that prepare Platelet Rich Plasma (PRP) products for extracorporeal use. See the device operator's manual for additional information and complete usage instructions. (1)

DOSAGE AND ADMINISTRATION

- ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is added to blood products collected for extracorporeal processing. (2)
- ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A may only be used with devices that prepare Platelet Rich Plasma (PRP) products for extracorporeal use. For instructions on the use of the solution see the device operator's manual. (2.1)
- Follow the directions for drawing ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A into a syringe for further processing of the collected blood product. (2.2)

DOSAGE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

- NOT FOR PREPARATION OF BLOOD PRODUCTS FOR TRANSFUSION OR FOR DIRECT INTRAVENOUS INFUSION. (4)

WARNINGS AND PRECAUTIONS

- Do not use the ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A unless the solution is clear and the container is intact and undamaged. Use aseptic technique throughout all procedures to ensure donor safety and quality. (5)

ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the injection of blood products containing citrate anticoagulant. The recipient of the blood product 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: 7/2023

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 intended for use only with devices that prepare Platelet Rich Plasma (PRP) products for extracorporeal use. *[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 blood products collected for extracorporeal processing. The solution is manually added to collected blood products to facilitate extracorporeal processing. The amount of solution added is specified by the manufacturer of the processing set. It is not intended for direct intravenous infusion.

For instructions on the use of the solution with the processing 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 solution bag. Do not use if the solution bag 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 drawing the* ANTICOAGULANT CITRATE DEXTROSE SOLUTION**

USP (ACD) SOLUTION A *from the solution bag.*

When directed by the processing set instructions and device operator's manual:

1. Open the foil pouch containing the solution by finding the notch in the foil overwrap and pulling down to present the clear overwrapped solution bag.
2. Open the clear overwrap material by holding the peelable tabs between your thumb and forefinger. Gently pull the peelable tabs along the top to open the overwrap at both corners. Once both corners are opened, gently peel along the length of the overwrap. Do not place the ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A solution bag into the sterile field. The clear overwrap is not considered a sterile barrier.
3. 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 solution 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. Solution showing cloudiness, haze, or particulate matter should not be used.
4. Aseptically prepare the Needleless Access Valve (NAV).
5. Using an appropriate syringe and luer, connect to the NAV.
6. Draw into the syringe the amount of ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A required by the processing set instructions and device operator's manual.
7. Remove the syringe from the NAV and proceed according to the processing set instructions and device operator's manual.

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

3 DOSAGE FORMS AND STRENGTHS

50 mL ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is a sterile solution in a polyolefin solution 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

NOT FOR PREPARATION OF BLOOD PRODUCTS FOR TRANSFUSION OR FOR DIRECT INTRAVENOUS INFUSION.

5 WARNINGS AND PRECAUTIONS

- Do not use the ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A unless the solution is clear and the container is intact and undamaged.
- Do not transfer the solution bag directly into the sterile field.
- Do not reuse. Discard unused or partially used solution bags.
- Discard the product if the Needleless Access Valve (NAV) does not function as intended.

- Aseptically prepare the NAV before use.

6 ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the injection of blood products containing citrate anticoagulant. The recipient of the blood product 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 studied in controlled clinical trials with specific populations.

11 DESCRIPTION

ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP (ACD) SOLUTION A is designed to be added to blood products collected for extracorporeal processing, to prevent platelet activation and coagulation as blood moves throughout the extracorporeal processing set.

The content of the solution bag is considered sterile. This product has a sterile fluid path only. The clear overwrap is not considered a sterile barrier. The solution is 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 solution bag is not made with natural rubber latex or PVC.

The solution bag is made from a polyolefin film. It contains materials that have been tested to demonstrate the suitability of the solution bag for storing pharmaceutical

solutions. The solution contact layer is a polyolefin. The solution bag is nontoxic and biologically inert. The solution bag is a closed system and is not dependent upon entry of external air during administration. The solution bag is covered with a clear overwrap to provide protection from the physical environment. The content of the solution bag is considered sterile. This product has a sterile fluid path only. The clear overwrap is not considered a sterile barrier.

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 sterile solution supplied in non-pyrogenic polyolefin solution bags. Each solution bag is individually wrapped in a clear overwrap. Each clear overwrap is then individually foil wrapped. Neither the clear overwrap nor the foil overwrap can be considered a sterile barrier. This product has a sterile fluid pathway only.

SIZE	CATALOG NUMBER	NDC NUMBER	
50 mL	40820	Case:	14537-820-03
		Foil:	14537-820-01
		Bag:	14537-820-00

STORAGE

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

Issued: July 2023

Manufactured by
Terumo BCT, Inc.
Lakewood, CO 80215

Made in UK

PRINCIPAL DISPLAY PANEL - 50 mL Bag Pouch Case Label

Anticoagulant Citrate Dextrose Solution USP (ACD) Solution A

Catalog # 40820
Polyolefin Bag
50 X 50 mL

NDC 14537-820-03

Indications for use: Anticoagulant intended for use only with devices that prepare Platelet
Rich Plasma (PRP) products for extracorporeal use. See Operator's Manuals for additional
information and complete usage instructions.

Caution: Only the solution bag fluid path is sterile and non-pyrogenic. Do not use unless the solution is clear and the container is intact and undamaged. Do not transfer solution bag directly into the sterile field. Sterilized with Steam. Rx only. Single use container. Not for preparation of blood products for transfusion or for direct intravenous
infusion.

Storage Conditions:
Room temperature (68° to 77°F, 20° to 25°C).
Avoid excessive heat. Protect from freezing. Protect from direct sunlight.

Each 10mL contains:
Citric Acid Monohydrate USP
0.08 g
Sodium Citrate Dihydrate USP
0.220 g
Dextrose Monohydrate USP
0.245 g
In Water for Injection USP
STERILE

Manufactured by TERUMO BCT, INC.
10811 West Collins Ave., Lakewood, Colorado 80215-4440, USA
Made in UK
LPN - 1000041011

Lot
Expiry Date

Anticoagulant Citrate Dextrose Solution USP (ACD) Solution A

Catalog # 40820 **Polyolefin Bag** **50 X 50 mL**

NDC 14537-820-03

Indications for use: Anticoagulant intended for use only with devices that prepare Platelet Rich Plasma (PRP) products for extracorporeal use. See Operator's Manuals for additional information and complete usage instructions.

Caution : Only the solution bag fluid path is sterile and non-pyrogenic. Do not use unless the solution is clear and the container is intact and undamaged. Do not transfer solution bag directly into the sterile field. Sterilized with Steam. Rx only. Single use container. Not for preparation of blood products for transfusion or for direct intravenous infusion.

Storage Conditions:
Room temperature (68° to 77°F, 20° to 25°C).
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Each 10mL contains:

Citric Acid Monohydrate USP	0.08 g
Sodium Citrate Dihydrate USP	0.220 g
Dextrose Monohydrate USP	0.245 g
In Water for Injection USP	

STERILE

Manufactured by **TERUMO BCT, INC.**
10811 West Collins Ave., Lakewood, Colorado 80215-4440, USA
Made in UK

LPN - 1000041011

Lot Expiry Date

ANTICOAGULANT CITRATE DEXTROSE (ACD-A)

dextrose monohydrate, sodium citrate, unspecified form, and citric acid monohydrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:14537-820
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	0.245 g in 10 mL
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR) (Sodium Cation - UNII:LYR4M0NH37)	Sodium Citrate, Unspecified Form	0.220 g in 10 mL
Citric Acid Monohydrate (UNII: 2968PHW8QP) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	0.08 g in 10 mL

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14537-820-03	50 in 1 CASE		
1	NDC:14537-820-01	1 in 1 POUCH		
1	NDC:14537-820-00	50 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	BA110057	07/18/2023	

Labeler - Terumo BCT, Ltd (233649834)

Registrant - Terumo BCT, Inc. (801679200)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo BCT, Ltd		233649834	LABEL(14537-820) , ANALYSIS(14537-820) , STERILIZE(14537-820) , MANUFACTURE(14537-820)

Revised: 7/2023 Terumo BCT, Ltd