

**ANTICOAGULANT CITRATE DEXTROSE A- anhydrous citric acid, dextrose monohydrate, and trisodium citrate dihydrate solution**  
**Citra Labs LLC**

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**ACD-A**

**Anticoagulant Citrate Dextrose Solution,**

**Solution A, U.S.P., PN 9350, 30 mL**

**NDC 23731-6051-3**

**Description**

Anticoagulant Citrate Dextrose Solution, Solution A, U.S.P., (ACD-A), is a sterile, non-pyrogenic solution of citric acid, sodium citrate, and dextrose, in water for injection. Each 10 mL of solution contains:

Citric Acid, anhydrous, 0.073 g  
USP

Sodium Citrate, dihydrate, 0.220 g  
USP

Dextrose, monohydrate, 0.245 g  
USP

Water for Injection, USP q.s.

pH: 4.5 – 5.5

⊗ Single patient use only, on a single occasion.

**Clinical Pharmacology**

ACD-A acts as an anticoagulant by the action of the citrate ion chelating free ionized calcium, thus making calcium unavailable to the coagulation system.

**Indications and Usage**

Anticoagulant Citrate Dextrose Solution, Solution A, U.S.P. (ACD-A), is intended for use as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP). Refer to the manufacturer's Operator's Manual of the Autologous PRP System for the Directions for Use.

**Contraindications**

NOT FOR DIRECT INTRAVENOUS INFUSION

## **Warnings**

NOT FOR DIRECT INTRAVENOUS INFUSION

## **Precautions**

### **General**

- Aseptic technique must be maintained at all times.
- ACD-A solution is a clear and colorless solution. If the product shows any cloudiness or turbidity, the product should be discarded.
- The closure system provides a biological barrier and should be intact – discard product if system is compromised.

### **Information for Patients**

None.

### **Carcinogenesis, mutagenesis, impairment of fertility**

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of ACD-A.

### **Pregnancy**

Long-term studies in animals have not been performed to evaluate the effects of ACD- A on pregnant women.

### **Pediatric Use**

The safety and effectiveness of ACD-A in children have not been established.

### **Adverse Reactions**

Not applicable. This product is used as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP).

### **Overdosage**

Not applicable. This product is used as an anticoagulant in the extracorporeal blood processing with Autologous PRP systems in production of platelet rich plasma (PRP).

### **Dosage and Administration**

Refer to the manufacturer's Operator's Manual of the Autologous PRP System for the Directions for Use.

### **Rx Only**

Caution: Federal Law (US) restricts this device to sale by or on the order of a Physician.

## How Supplied

Anticoagulant Citrate Dextrose Solution, Solution A, U.S.P., (ACD-A)

REF	SIZE	CASE
PN 9350-10	30 mL	10 Vials/Case
PN 9350-25	30 mL	25 Vials/Case

It is recommended that the product be stored at ambient room temperature, 24 °C (75 °F); however, the product can be stored between 15 °C (59 °F) and 30 °C (86 °F). Protect from freezing and exposure to excessive heat should be minimized.

Manufactured & Distributed by:

**Citra**Labs™

55 Messina Drive, Braintree, MA 02184

Phone Number: 1-800-299-3411

Authorized Representative:

*Biomet Global Supply Chain Center B.V.*

*Hazeldonk 6530*

*4836 LD Breda*

*The Netherlands*



## PRINCIPAL DISPLAY PANEL - 10 Vial Case Label

**C E 0044**

**ACD-A**

**Anticoagulant Citrate Dextrose Solution,**

**10 Vials / Case    Solution A, U.S.P., ACD-A, 30 mL**

**REF PN 9350-10**

## **WARNING:** NOT FOR DIRECT INTRAVENOUS INFUSION

Used as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP). Refer to PRP Systems manufacturer's Directions for Use.

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A Biomet Inc. Company.

Citra Labs, LLC.  
55 Messina Drive, Braintree, MA 02184  
1-800-299-3411

## EC REP

Authorized Representative:  
Biomet Global Supply Chain Center B.V.  
Hazeldonk 6530  
4836 LD Breda  
The Netherlands



### STERILE • NON-PYROGENIC

Composition per 10 mL of Solution:

Citric Acid, (Anhydrous), U.S.P. 0.073 g.

Sodium Citrate, (Dihydrate), U.S.P. 0.220 g.

Dextrose, (Monohydrate), U.S.P. 0.245 g.

**CAUTION:** Single Procedure Use-Discard Unused Portion

Do Not Use Unless Solution is Clear and Seal is Intact.

Store Between 15 °C - 30 °C (59 °F - 86 °F).

**RX Only:**

### EXP DATE

LOT

LA9350-10B 01/20



## ACD-A

Anticoagulant Citrate Dextrose Solution,

**10 Vials / Case** Solution A, U.S.P., **ACD-A, 30 mL**

REF PN 9350-10

NDC 23731-6051-3

**WARNING:** NOT FOR DIRECT INTRAVENOUS INFUSION

Used as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP). Refer to PRP Systems manufacturer's Directions for Use.



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### STERILE • NON-PYROGENIC

Composition per 10 mL of Solution:

Citric Acid, (Anhydrous), U.S.P. 0.073 g.

Sodium Citrate, (Dihydrate), U.S.P. 0.220 g.

Dextrose, (Monohydrate), U.S.P. 0.245 g.

**CAUTION:** Single Procedure Use-Discard Unused Portion

Do Not Use Unless Solution is Clear and Seal is Intact.

Store Between 15 °C - 30 °C (59 °F - 86 °F).

**RX Only:**

EXP DATE



LOT

LA9350-10B 01/20

## PRINCIPAL DISPLAY PANEL - 25 Vial Case Label

C E 0044

**ACD-A**

**Anticoagulant Citrate Dextrose Solution,**

**25 Vials / Case    Solution A, U.S.P., ACD-A, 30 mL**

**REF** PN 9350-25

**WARNING:** NOT FOR DIRECT INTRAVENOUS INFUSION

Used as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP). Refer to PRP Systems manufacturer's Directions for Use.

Manufactured & Distributed by:

**Citra**Labs

A Biomet Inc. Company.

Citra Labs, LLC.

55 Messina Drive, Braintree, MA 02184

1-800-299-3411

**EC REP**

Authorized Representative:

Biomet Global Supply Chain Center B.V.

Hazeldonk 6530

4836 LD Breda

The Netherlands



**STERILE • NON-PYROGENIC**

Composition per 10 mL of Solution:

Citric Acid, (Anhydrous), U.S.P. 0.073 g.

Sodium Citrate, (Dihydrate), U.S.P. 0.220 g.

Dextrose, (Monohydrate), U.S.P. 0.245 g.

**CAUTION:** Single Procedure Use-Discard Unused Portion

Do Not Use Unless Solution is Clear and Seal is Intact.

Store Between 15 °C - 30 °C (59 °F - 86 °F).

**RX Only:**

**EXP DATE**

LOT

LA9350-25 01/20

**ACD-A****Anticoagulant Citrate Dextrose Solution,****25 Vials / Case Solution A, U.S.P., ACD-A, 30 mL**

REF PN 9350-25

NDC 23731-6051-3

**WARNING: NOT FOR DIRECT INTRAVENOUS INFUSION**

Used as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP). Refer to PRP Systems manufacturer's Directions for Use.

**STERILE • NON-PYROGENIC**

Composition per 10 mL of Solution:

Citric Acid, (Anhydrous), U.S.P. 0.073 g.

Sodium Citrate, (Dihydrate), U.S.P. 0.220 g.

Dextrose, (Monohydrate), U.S.P. 0.245 g.

**CAUTION:** Single Procedure Use-Discard Unused Portion  
Do Not Use Unless Solution is Clear and Seal is Intact.  
Store Between 15 °C - 30 °C (59 °F - 86 °F).

**RX Only:**

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EXP DATE



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LA9350-25B 01/20

## ANTICOAGULANT CITRATE DEXTROSE A

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

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:23731-6051
<b>Route of Administration</b>	EXTRACORPOREAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R00K)	DEXTROSE MONOHYDRATE	0.245 g in 10 mL
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.073 g in 10 mL
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.22 g in 10 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23731-6051-3	30 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:23731-6051-1	10 in 1 CASE		
3	NDC:23731-	30 mL in 1 VIAL, SINGLE-USE; Type 0: Not a		

4	6051-3	Combination Product		
3	NDC:23731-6051-2	25 in 1 CASE		
3	NDC:23731-6051-3	30 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN020037	08/26/2003	

**Labeler -** Citra Labs LLC (962863838)

### Establishment

Name	Address	ID/FEI	Business Operations
Citra Labs LLC		962863838	MANUFACTURE(23731-6051)