

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

**Citra Labs**

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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, USP    | 0.073 g |
| Sodium Citrate, dihydrate, USP | 0.220 g |
| Dextrose, monohydrate, USP     | 0.245 g |
| 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)

| <b>REF</b> | <b>SIZE</b> | <b>CASE</b>   |
|------------|-------------|---------------|
| 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:

**CitraLabs™**

55 Messina Drive, Braintree, MA 02184

Phone Number: 1-800-299-3411

Authorized Representative:

*Biomet U.K. Ltd.*

*Waterton Industrial Estate*

*Bridgend, South Wales, CF31 3XA*

*Great Britain*

*United Kingdom*

*Phone 441.65.66.55.221*



**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.

Manufactured & Distributed by:

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A Biomet Biologics Company

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55 Messina Drive, Braintree, MA 02184

1-800-299-3411

**EC REP**

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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 02/15



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EXP DATE 

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LA9350-10B 02/15

## 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**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b>  |
|---|--------------------------|------------------|
| <b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)           | 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**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                                     | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|--|-----------------------------|---------------------------|
| 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   |                             |                           |
| 2        | NDC:23731-6051-3 | 30 mL in 1 VIAL, SINGLE-USE; Type 0: Not a 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**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| NDA                       | BN020037  | 08/26/2003                  |                           |

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

| <b>Name</b> | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|-------------|----------------|---------------|----------------------------|
| Citra Labs  |                | 962863838     | manufacture(23731-6051)    |