

**ACD-A- anticoagulant citrate dextrose solution formula a solution
Fenwal, Inc.**

Anticoagulant Citrate Dextrose Solution USP (ACD) Formula A

CAUTION-

DO NOT REMOVE UNIT FROM OVERWRAP UNTIL READY FOR USE
THE OVERWRAP IS A MOISTURE BARRIER
THE INNER BAG MAINTAINS THE STERILITY OF THE PRODUCT
STORE AT CONTROLLED ROOM TEMPERATURE

**CODE 4B7898Q
NDC 0942-0641-03**

500 mL

Fenwal™

Anticoagulant Citrate Dextrose Solution USP (ACD) Formula A

EACH 100 mL CONTAINS 2.45 g DEXTROSE (MONOHYDRATE) USP 2.2 g SODIUM
CITRATE (DIHYDRATE) USP 730 mg CITRIC ACID (ANHYDROUS) USP

STERILE , NONPYROGENIC

STERILIZED BY STEAM

SINGLE USE CONTAINER

DISCARD UNUSED PORTION

FOR USE WITH CYTAPHERESIS DEVICE ONLY

NOT FOR DIRECT INTRAVENOUS INFUSION

DO NOT USE UNLESS SOLUTION IS CLEAR AND NO LEAKS ARE DETECTED

AFTER REMOVING OVERWRAP CHECK FOR MINUTE LEAKS BY SQUEEZING INNER BAG
FIRMLY

IF LEAKS ARE FOUND DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED

DISPOSE OF CONTAINER APPROPRIATELY

SEE CARTON FOR ADDITIONAL PRODUCT AND COUNTRY SPECIFIC INFORMATION

Rx only

PL 146 PLASTIC

Manufactured by:
Baxter Healthcare Corporation
65 Pitts Station Road
Marion, North Carolina 28752

MADE IN USA 07-25-57-867 REV: B

Manufactured for:



Fenwal, Inc.
Lake Zurich, IL 60047 USA

PACKAGE/LABEL DISPLAY PANEL

LOT

EXP

CAUTION- DO NOT REMOVE UNIT FROM OVERWRAP UNTIL READY FOR USE THE OVERWRAP IS A MOISTURE BARRIER THE INNER BAG MAINTAINS THE STERILITY OF THE PRODUCT STORE AT CONTROLLED ROOM TEMPERATURE

1 — **CODE 4B7898Q** **500 mL** **-1**
NDC 0942-0641-03

2 —  **Anticoagulant Citrate** **-2**
Dextrose Solution USP
(ACD) Formula A

3 — EACH 100 mL CONTAINS 2.45 g DEXTROSE **-3**
(MONOHYDRATE) USP 2.2 g SODIUM CITRATE
(DIHYDRATE) USP 730 mg CITRIC ACID (ANHYDROUS) USP
STERILE, NONPYROGENIC STERILIZED BY STEAM
SINGLE USE CONTAINER DISCARD UNUSED PORTION
FOR USE WITH CYTAPHERESIS DEVICE ONLY

4 — **NOT FOR DIRECT INTRAVENOUS INFUSION** **-4**
DO NOT USE UNLESS SOLUTION IS CLEAR AND NO LEAKS ARE DETECTED
AFTER REMOVING OVERWRAP CHECK FOR MINUTE LEAKS BY SQUEEZING INNER BAG FIRMLY IF LEAKS ARE FOUND DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED
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[Enter

Package/Label Display Panel here]

ACD-A

anticoagulant citrate dextrose solution formula a solution

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:0942-0641 |
| Route of Administration | INTRAVENOUS | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------------|----------------------|
| Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SLOG7ROOK) | Dextrose Monohydrate | 12.25 g in 500 mL |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) (Anhydrous Citric Acid - UNII:XF417D3PSL) | SODIUM CITRATE, UNSPECIFIED FORM | 11 g in 500 mL |
| Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL) | Anhydrous Citric Acid | 3.65 g in 500 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|----------|
| Water (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0942-0641-03 | 500 mL in 1 BAG; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA | BN160918 | 03/01/2007 | |

Labeler - Fenwal, Inc. (794519020)

Registrant - Fenwal, Inc. (794519020)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|---------|-----------|------------------------|
| Baxter Healthcare Corporation | | 059140764 | MANUFACTURE(0942-0641) |

