

CPDA-1 - anticoagulant citrate phosphate dextrose adenine solution
Fenwal, Inc.

Anticoagulant Citrate Phosphate Dextrose Adenine Solution, USP (CPDA-1) Blood-Pack Unit

Instructions for Blood Collection Using Anticoagulant Citrate Phosphate Dextrose Adenine Solution, USP (CPDA-1) Blood-Pack Units

Integral Donor Tube (IDT)

Use aseptic technique.

This product has components which contain natural rubber latex.

Precaution: Do not use unless anticoagulant is clear.

1. Identify Blood-Pack unit using appropriate donor identification system. Confirm that all numbered tubing of each Blood-Pack unit contains its own identical segment numbers.
2. Adjust donor scale to desired collection weight.
3. Position primary container on the donor scale as far as possible below donor arm and clamp donor tubing with hemostat.
4. Apply pressure to donor's arm and disinfect site of venipuncture.
5. If blood pressure cuff is used, inflate to approximately 60 mmHg.
6. Remove needle cover per instructions below:
 - (a) Holding the hub and cover near the tamper-evident seal, twist cover 1/4 turn to break seal.
 - (b) Remove needle cover, being careful not to drag the cover across the needle point.

Perform venipuncture, appropriately secure donor needle and/or tubing and release hemostat.

7. **Mix blood and anticoagulant at several intervals during collection and immediately after collection.**
8. Collect the appropriate volume based on Blood-Pack unit used. Note: The volume of anticoagulant is sufficient for the blood collection indicated on Blood-Pack unit \pm 10%.
9. Apply hemostat to donor tubing.
10. As appropriate, release pressure on the donor's arm, collect donor samples following established procedures and withdraw donor needle.

Precaution: Use care to avoid accidental needle sticks. One of the Fenwal Needle Protector Systems may be used to reduce the risk of needle stick injury.

11. Strip blood from donor tubing into primary container, mix and allow the tubing to refill; repeat once. Seal at X marks on donor tubing to provide numbered aliquots of anticoagulated blood for typing or crossmatching.
12. Discard needle into an appropriate biohazardous waste container following established procedures.
13. Store suspended CPDA-1 Whole Blood/ Red Blood Cells between 1 and 6° C.
14. Infuse CPDA-1 Whole Blood/Red Blood Cells within 35 days of collection.

For further processing with multiple Blood-Pack units, use standard component processing techniques.

Baxter Healthcare Corporation

Fenwal Division
Deerfield, IL 60015 USA

Made in USA

07-19-29-257
Iss. May 2002

Baxter, Fenwal and Blood-Pack are trademarks of Baxter International Inc., registered in the U.S. Patent and Trademark Office.

PACKAGE/LABEL DISPLAY PANEL

Code 4R6312

20 Units

Baxter

Fenwal

Anticoagulant Citrate Phosphate Dextrose Adenine Solution, USP (CPDA-1) Blood-Pack Unit

Triple For the Collection and Processing of 450 mL Blood

Integral Donor Tube, 16 ga. Ultra Thin Wall Needle

Each unit consists of a PL 146 Plastic primary container with 63 mL of CPDA-1 solution containing 2 g Dextrose (monohydrate) USP, 1.66 g Sodium Citrate (dihydrate) USP, 188 mg Citric Acid (anhydrous) USP, 140 mg Monobasic Sodium Phosphate (monohydrate) USP and 17.3 mg Adenine USP, pH may have been adjusted with sodium hydroxide; two empty 400 mL PL 1240 plastic Transfer Pack Containers.

Rx only

Sterile, nonpyrogenic fluid path
See instructions for use.

Store at room temperature.

- Open pouch by tearing across at notch.
- Unused units in open **foil** pouch may be kept up to 60 days by folding and **securing** open end of **foil** pouch to prevent possible loss of moisture.
- Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.
- Units removed from the **foil** pouch must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 4 days must be discarded.

U.S. Pat. Nos. 4,402,682; 4,413,992; 4,505,708; 4,508,534; 4,574,456; 5,314,421; 5,507,525.

Baxter, Fenwal, Blood-Pack, PL 146 and Transfer Pack are trademarks of Baxter International Inc.; Baxter, Fenwal and Blood-Pack are registered in the U.S. Patent and Trademark Office.

Baxter Healthcare Corporation

Fenwal Division
Deerfield, IL 60015 USA

Made in USA

07-28-35-996
02/2003

Baxter**Fenwal**

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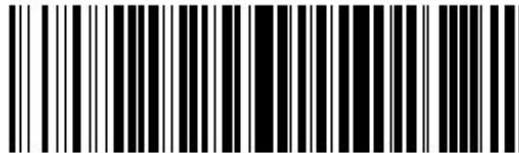
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+H1604R631220

CPDA-1

anticoagulant citrate phosphate dextrose adenine solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0942-9304
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE -	Dextrose Monohydrate	2 g in 63 mL

UNII:5SL0G7R0OK)	Dextrose Monohydrate	2 g in 63 mL
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	1.66 g in 63 mL
Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	188 mg in 63 mL
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Monohydrate	140 mg in 63 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	17.3 mg in 63 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0942-9304-03	63 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	BN770420	03/01/2007	

Labeler - Fenwal, Inc. (794519020)

Establishment

Name	Address	ID/FEI	Business Operations
Fenwal International, Inc.		091164590	MANUFACTURE(0942-9304)

Revised: 11/2019

Fenwal, Inc.