ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) BLOOD-PACK UNITS IN PL 146 PLASTIC - anticoagulant citrate phosphate dextrose (cpd) solution solution
Fenwal, Inc.

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit

4R0012MC, 4R0837MC, 4R0112MC

Fenwal Blood-Pack Units
Rx only
With Integral Donor Tube Using ACD or CPD and Fenwal HighFlo Needle

Instructions for Use
Collection Procedure:
Use aseptic technique.
Precaution: Do not use unless solution 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 from donor scale as far as possible below donor arm and clamp donor tubing.
4. Following blood center procedures, apply pressure to donor's arm and disinfect site of venipuncture.
5. Remove HighFlo[1] needle cover per instructions below:
a) Holding the hub and cover near the tamper-evident seal, twist cover and hub in opposite directions to break seal.
b) Remove needle cover, being careful not to drag the cover across the needle point.
Following blood center procedures, perform venipuncture, appropriately secure donor needle and/or tubing and release clamp.
6. **Mix blood and anticoagulant at several intervals during collection and immediately after collection.**
7. 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 ± 10%.
8. Apply clamp to donor tube.
9. As appropriate, release pressure on the donor's arm, collect donor samples following established procedures and withdraw donor needle.
10. **Withdrawal of needle into needle guard.**
Precaution: The needle guard must be held stationary while the needle is withdrawn into it.
a) Hold sides of needle guard near the front, between the index finger and thumb. Pull the hub back smoothly until the needle is completely enclosed and securely locked into the needle guard.
b) Confirm the needle is completely enclosed and securely locked into the needle guard.
11. Strip blood from donor tubing into 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 in needle guard into an appropriate biohazardous waste container following established procedures.
13. Store filled unit between 1 and 6° C.
14. Infuse blood within 21 days of collection.
Store at Controlled Room Temperature. Protect from freezing. Avoid excessive heat.
Definition of "Controlled Room Temperature":
"A temperature maintained thermostatically that encompasses the usual and customary working

environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15°C and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C are permitted as long as they do not exceed 24 hours ... The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the non isothermal effects of storage temperature variations."

Reference: United States Pharmacopeia, General Notices. United States Pharmacopeial Convention, Inc. 12601 Twinbrook Parkway, Rockville, MD.

Symbols with Definitions


Caution, consult instructions for use

Sterilized by steam
Sterile fluid path


Non-pyrogenic fluid path


Do not reuse


Do not vent

Code

Lot


This way up

[1] Van der Meer, P.F., & de Korte, D. "Increase of blood donation speed by optimizing the needle-to-tubing connection: an application of donation software." Vox Sanguinis 2009, 97: 21-25

Manufacturer
Fresenius Kabi AG
61346 Bad Homburg / Germany
www.fresenius-kabi.com
1-800-933-6925

47-23-13-621 REV: A

PACKAGE/LABEL DISPLAY PANEL

Code 4R0837MC

1 Unit
Fresenius Kabi

Fenwal Blood-Pack Unit
Single

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD)
For Collection of 250 mL Blood
Integral Donor Tube, 16 ga. Ultra Thin Wall Fenwal HighFlo Needle

Rx only

Each unit consists of a primary container with 35 mL of CPD solution containing 921 mg Sodium Citrate (dihydrate) USP, 893 mg Dextrose (monohydrate) USP, 105 mg Citric Acid (anhydrous) USP, 78 mg Monobasic Sodium Phosphate (monohydrate) USP. pH may have been adjusted with sodium hydroxide.

Sterile, non-pyrogenic fluid path.
See instructions for use.
Single Use Only

Store at Controlled Room Temperature (refer to direction insert). Protect from freezing. Avoid excessive heat.

- Open pouch by tearing across at notch.
- Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.
- 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, provided:

I) Units are not removed from **foil** pouch, or
II) Unused units removed from **foil** pouch are returned to the foil pouch within 12 hours. Units may be removed from the pouch and returned only once.

- Units removed from the **foil** pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 96 hours must be discarded.

Manufacturer
Fresenius Kabi AG
61346 Bad Homburg / Germany
www.fresenius-kabi.com
Made in US

47-28-12-755 REV: A

Code 4R0837MC ← To Open Tear Across at Notch → 1 Unit

FRESENIUS KABI

Fenwal Blood-Pack Unit Single

Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD)

For Collection and Processing of 250 mL Blood

Integral Donor Tube, 16 ga. Ultra Thin Wall Fenwal HighFlo Needle

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ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) BLOOD-PACK UNITS IN PL 146 PLASTIC

anticoagulant citrate phosphate dextrose (cpd) solution solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0942-9201
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	921 mg in 35 mL
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	893 mg in 35 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	105 mg in 35 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	78 mg in 35 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0942-9201-01	35 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	BN170401	03/01/2007	

Labeler - Fenwal, Inc. (794519020)

Establishment

Name	Address	ID/FEI	Business Operations
Fenwal International, Inc.		091164590	MANUFACTURE(0942-9201)

Revised: 9/2019 Fenwal, Inc.