

LEUKOTRAP WB SYSTEM- leukotrap wb system
Haemonetics Corporation

Leukotrap WB Sytem

CP2D Anticoagulant Solution and AS-3 Solution may be used with Haemonetics apheresis devices. See the Haemonetics Operation Manual for full operating instructions.

Prior to use of the solutions, check the solutions for leaks by squeezing each of the bags firmly. If leaks are found, discard the solution.

HAEMONETICS®

LEUKOTRAP® WB SYSTEM

CP2D/AS-3 Triple Blood Bag Unit with In-Line WBF Filter (WBF2) and Sampling System

For collection of 450 ml of whole blood and preparation of red blood cells and plasma with pre-storage leukocyte reduction

Each unit consists of a collection bag with 63 ml of CP2D solution, an additive bag with 100 ml of AS-3 solution, two empty bags, and a sample diversion pouch. Each 63 ml of CP2D solution contains 3.21 g dextrose (monohydrate), USP; 1.66 g sodium citrate (dihydrate), USP; 0.206 g citric acid (monohydrate), USP; and 0.140 g monobasic sodium phosphate (monohydrate), USP. Each 100 ml of AS-3 solution contains 1.10 g dextrose (monohydrate), USP; 0.588 g sodium citrate (dihydrate), USP; 0.410 g sodium chloride, USP; 0.276 g monobasic sodium phosphate (monohydrate), USP; 0.042 g citric acid (monohydrate), USP; and 0.030 g adenine, USP.

Sterile, nonpyrogenic fluid path. Sterilized by steam. Rx only. See accompanying directions for use. Store at room temperature. Unused bags in opened pouches may be kept 30 days by folding and SECURING open end of pouch to prevent possible loss of moisture.

SYSTÈME LEUKOTRAP® WB

Poche de sang triple CP2D/AS-3 avec filtre WBF (WBF2) en ligne et système d'échantillonnage

Pour le prélèvement de 450 ml de sang total et à la préparation globules rouges et de plasma avec déleucocytation avant conservation

Chaque dispositif comprend un sac de prélèvement contenant 63 ml de solution CP2D, un sac contenant 100 ml de solution additive AS-3, deux sacs vides, et une pochette de dérivation, 63 ml de solution CP2D contient 3,21 g de dextrose (monohydraté), USP; 1,66 g de citrate de sodium (bihydraté), USP; 0,206 g d'acide citrique (monohydraté), USP; et 0,140 g de phosphate de sodium monobasique (monohydraté), USP. 100 ml de solution AS-3 contient 1,10 g de dextrose (monohydraté), USP; 0,588 g de citrate de sodium (bihydraté), USP; 0,410 g de chlorure de sodium, USP; 0,276 g de phosphate de sodium monobasique (monohydraté), USP; 0,042 g d'acide citrique (monohydraté), USP; et 0,030 g d'adénine, USP.

Trajet stérile, apyrogène. Stérilisé à la vapeur. Sur prescription uniquement. Lire les directives accompagnant ce produit. Conserver à température ambiante. Les sacs non utilisés gardés à l'intérieur de l'enveloppe d'aluminium ouverte peuvent être entreposés pendant 30 jours si l'on plie et ATTACHE l'extrémité de l'enveloppe afin d'éviter la perte d'humidité.

3 Units/Unités

REF 726-63Q

Manufactured for:
Haemonetics Corporation
400 Wood Road, Braintree,
MA 02184, USA
By: Haemonetics Manufacturing Inc.
1630 Industrial Park Street
Covina, CA 91722, USA
www.haemonetics.com
800-537-2802



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(TMPL: 128100-00 AA)



(01)20887691313466(30)03(17)000000(10)000000

LEUKOTRAP WB SYSTEM

leukotrap wb system kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53157-262
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53157-262-01	1 in 1 KIT; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	0 BAG	1 mL in 63
Part 2	0 BAG	1 mL in 100

Part 1 of 2

ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE

anticoagulant citrate phosphate double dextrose injection, solution

Product Information

Route of Administration	INTRAVENOUS
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE - UNII:IY9XDZ35W2)	DEXTROSE	3.21 g in 63 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.206 g in 63 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	1.66 g in 63 mL
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	0.14 g in 63 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		63 mL in 1 BAG; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN820915		

Part 2 of 2

ADDITIVE SOLUTION - 3

additive solution - 3 injection, solution

Product Information

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ADENINE (UNII: JAC85A2161) (ADENINE - UNII:JAC85A2161)	ADENINE	0.03 g in 100 mL
DEXTROSE (UNII: IY9XDZ35W2) (DEXTROSE, UNSPECIFIED FORM - UNII:IY9XDZ35W2)	DEXTROSE	1.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	0.276 g in 100 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	0.588 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.41 g in 100 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.042 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		100 mL in 1 BAG; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN820915	09/23/1983	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN820915	09/22/1983	

Labeler - Haemonetics Corporation (057827420)

Establishment

Name	Address	ID/FEI	Business Operations
Haemonetics Manufacturing Inc		078598396	manufacture(53157-262)

Revised: 1/2022

Haemonetics Corporation