

AS 3- dextrose monohydrate, sodium citrate, sodium chloride, sodium phosphate, monobasic, monohydrate, citric acid monohydrate and adenine injection, solution

Terumo BCT Ltd

Additive Solution Formula 3

Catalog # 777965-000

6 x 6 x 100 mL units

NDC 14537-966-10

Canada DIN 02324393

Intended for use only with Trima and Trima Accel automated red blood cell apheresis devices and Atreus Whole Blood Processing System. See Operator's Manuals for additional information and complete usage instructions.

Sterile. Non-pyrogenic. Do not use unless the solution is clear and the container is intact. Rx only.
Single use container.

Caution: Not for direct intravenous infusion.

Recommended storage

Room temperature.

Avoid excessive heat. Protect from freezing.

Each 100 mL contains:

Dextrose Monohydrate USP	1.10 g
Sodium Citrate Dihydrate USP	0.588 g
Sodium Chloride USP	0.410 g
Monobasic Sodium Phosphate Monohydrate USP	0.276 g
Citric Acid Monohydrate USP	0.042 g
Adenine USP	0.030 g
In Water for Injection USP	

Manufactured by Terumo BCT, Inc.

10811 W. Collins Ave., Lakewood CO 80215, USA

Dist in Canada: Terumo BCT (Canada), Inc., 4 Robert Speck Pkwy,
Ste. 1500, Mississauga, ON, Canada L4Z1S1

TERUMOBCT

777965-065

Lot

Expiry Date

PRINCIPAL DISPLAY PANEL - 100 mL Label

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:14537-966
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextrose Monohydrate (UNII: LX22YL083G) (Anhydrous Dextrose - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.1 g in 100 mL
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) (Anhydrous Citric Acid - UNII:XF417D3PSL)	SODIUM CITRATE, UNSPECIFIED FORM	0.588 g in 100 mL
Sodium Chloride (UNII: 451W47IQ8X) (Chloride Ion - UNII:Q32ZN48698)	Sodium Chloride	0.41 g in 100 mL
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN) (Phosphate Ion - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Monohydrate	0.276 g in 100 mL
Citric Acid Monohydrate (UNII: 2968PHW8QP) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	0.042 g in 100 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	0.03 g in 100 mL

Packaging

Marketing Marketing

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14537-966-10	6 in 1 CASE		
1		6 in 1 POUCH		
1		100 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NDC:14537-966-20	30 in 1 CASE		
2		200 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN001214	05/29/2002	

Labeler - Terumo BCT Ltd (233649834)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo BCT Ltd.		233649834	MANUFACTURE(14537-966) , STERILIZE(14537-966) , LABEL(14537-966) , ANALYSIS(14537-966)

Revised: 12/2018

Terumo BCT Ltd