

**SODIUM CITRATE BLOOD PACK UNITS, (PL 146 PLASTIC)- anticoagulant sodium citrate solution solution**

**Fresenius Kabi USA, LLC**

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**PACKAGE/LABEL PRINCIPAL DISPLAY PANEL**

NDC 63323-505-74

FUM 4092 1x 250mL

Fresenius Kabi Rx only  
freeflex

**Anticoagulant Sodium Citrate Solution, USP**

EACH 100 mL CONTAINS 4 g SODIUM CITRATE (DIHYDRATE) USP pH ADJUSTED WITH CITRIC ACID STERILIZED USING STEAM STERILE FLUID PATH NONPYROGENIC FOR USE WITH CYTAPHERESIS DEVICE ONLY

NOT FOR DIRECT INTRAVENOUS INFUSION  
DO NOT REUSE DO NOT VENT DISCARD UNUSED PORTION DO NOT USE UNLESS SOLUTION IS CLEAR DO NOT USE IF PRODUCT STERILE BARRIER SYSTEM IS COMPROMISED AFTER REMOVING OVERWRAP CHECK FOR MINUTE LEAKS BY SQUEEZING INNER BAG FIRMLY IF LEAKS ARE FOUND DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED REMOVE RED TAB FOR PRODUCT USE DO NOT USE IF TABS ARE DAMAGED

**CAUTION**—DO NOT REMOVE UNIT FROM OVERWRAP UNTIL READY FOR USE

THE OVERWRAP IS A MOISTURE BARRIER  
THE INNER BAG MAINTAINS STERILITY OF THE PRODUCT STORE AT CONTROLLED ROOM TEMPERATURE  
PROTECT FROM FREEZING. AVOID EXCESSIVE HEAT

MANUFACTURING FACILITY/  
MANUFACTURED BY  
**FRESENIUS KABI NORGE AS**  
NO-1753 HALDEN, NORWAY  
MADE IN NO

MANUFACTURER  
**FRESENIUS KABI AG**  
61346 BAD HOMBURG,  
GERMANY

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www.fresenius-kabi.com  
FUM 4092 01-69-19-001

NDC No. 63323-505-74

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**FRESENIUS  
KABI**

**Rx only**

free flex<sup>®</sup>

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FUM 4092 01-69-19-001

### SODIUM CITRATE BLOOD PACK UNITS, (PL 146 PLASTIC)

anticoagulant sodium citrate solution solution

#### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63323-505
Route of Administration	INTRAVENOUS		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	4 g in 100 mL
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### Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63323-505-74	250 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	BN770923	09/29/2014	

**Labeler** - Fresenius Kabi USA, LLC (608775388)

**Registrant** - Fresenius Kabi USA, LLC (608775388)

### Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi Norge AS		731170932	MANUFACTURE(63323-505)