

**ANTICOAGULANT SODIUM CITRATE- trisodium citrate dihydrate solution
LABORATORIOS GRIFOLS SA**

Anticoagulant Sodium Citrate

ANTICOAGULANT SODIUM CITRATE 4% w/v SOLUTION USP

Rx only 250 mL

Intended for use only with automated apheresis devices.

Each 100 mL contains:

**Sodium Citrate (Dihydrate), USP 4.0 g
(pH adjusted with Citric Acid, Monohydrate, USP)**

CAUTION

Not for direct intravenous infusion. The pouch is a moisture barrier. Do not use unless solution is clear and no leaks detected. Single use container. Discard unused portion.

STERILE, nonpyrogenic fluid path.

RECOMMENDED STORAGE:

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Brief exposure up to 40°C (104°F) does not adversely affect the product. Protect from freezing.

Laboratorios Grifols, S. A.

SPAIN

Revision: 10/2019

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 76297-006-03

***Anticoagulant Sodium Citrate 4% w/v
Solution, USP 250 mL***

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LOT XXXXXX EXP YYYY-MM

30 x 250 mL

Num.:

GRIFOLS
Laboratorios Grifols, S. A. SPAIN


NDC 76297-006-03

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LOT XXXXXX EXP YYYY-MM 1002315

30 x 250 mL



(01)00376297006033(17)YYMMDD(10)XXXXXX

GRIFOLS
Laboratorios Grifols, S.A. SPAIN

Num.:

LOT: XXXXXX **EXP:** YYYY-MM

NDC 76297-006-02

**Anticoagulant Sodium Citrate 4% w/v
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Laboratorios Grifols, S. A. SPAIN

GRIFOLS

LOT: XXXXXX

EXP: YYYY-MM

SPACE RESERVED FOR LOT
AND EXP ENCODING

INTERNAL REFERENCE



(01)00376297006026

NDC 76297-006-02

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4000601



Laboratorios Grifols, S.A. SPAIN

GRIFOLS

ANTICOAGULANT SODIUM CITRATE

trisodium citrate dihydrate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76297-006
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety

Base of

Ingredient Name	Basis of Strength	Strength
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76297-006-03	30 in 1 CARTON		
1	NDC:76297-006-02	250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:76297-006-01	28 in 1 CARTON		
2	NDC:76297-006-02	250 mL in 1 BAG; Type 0: Not a Combination Product		
3	NDC:76297-006-04	39 in 1 CARTON		
3	NDC:76297-006-02	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
ANDA	BA125697	10/25/2019	

Labeler - LABORATORIOS GRIFOLS SA (461842294)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS GRIFOLS SA		463719725	manufacture(76297-006) , pack(76297-006) , label(76297-006)

Establishment

Name	Address	ID/FEI	Business Operations
LABORATORIOS GRIFOLS SA		461842294	analysis(76297-006)