

ANTICOAGULANT SODIUM CITRATE- trisodium citrate dihydrate solution CSL Plasma Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ANTICOAGULANT SODIUM CITRATE 4 % W/V SOLUTION USP safely and effectively. See full prescribing information for ANTICOAGULANT SODIUM CITRATE 4 % W/V SOLUTION USP.

ANTICOAGULANT SODIUM CITRATE 4 % W/V SOLUTION USP

**Sterile Fluid
PVC Bag**

Initial U.S. Approval: 1978

INDICATIONS AND USAGE

ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP is intended for use only for the anticoagulation of whole blood as part of automated apheresis procedures. (1)

DOSAGE AND ADMINISTRATION

- ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP is added to tubing sets during apheresis procedures. (2)
- ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP may only be used with apheresis devices. For instructions on the use of the solution see the apheresis device operator's manual. (2.1)
- Follow the directions for connecting the ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP bag to the apheresis system. (2.2)

DOSAGE FORMS AND STRENGTHS

- 250 mL sterile fluid in a PVC bag. (3)

CONTRAINDICATIONS

- DO NOT INFUSE ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP DIRECTLY TO THE DONOR. (4)

WARNINGS AND PRECAUTIONS

- Verify that the ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP has been securely attached to the anticoagulant (AC) line on the system tubing set. Use aseptic technique throughout all procedures to ensure donor safety and quality.
- Single-use container, do not reuse. Discard any unused or partially used product.
- Rx only (5)

ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the infusion and return of blood containing citrate anticoagulant. The recipient of the blood containing citrate should be monitored for the signs and symptoms of citrate toxicity. (6)

To report SUSPECTED ADVERSE REACTIONS, contact CSL Plasma Inc. at 1-833-275-0044 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP has not been studied in controlled clinical trials with specific populations. (7)

Revised: 5/2022

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FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP is intended for use only for the anticoagulation of whole blood as part of automated apheresis procedures. [See *Dosage and Administration (2).*]

2. DOSAGE AND ADMINISTRATION

2.1. General Dosing Information

ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP is added to tubing sets during apheresis procedures. The solution bag is connected to the tubing set in an apheresis collection. The recommended dose is determined by the apheresis device and metered into the tubing set by the apheresis device. It is not intended for direct intravenous infusion.

For instructions on the use of the solution with the apheresis device and tubing set, see the device operator's manual.

2.2. Administration

- Ensure solution is the ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP and is within the expiration date
- Inspect the bag. Do not use if the container is damaged, leaking, or if there is any visible sign of deterioration
- Use only if solution is clear and free of particulate matter
- Protect from sharp objects.

Directions for connecting the ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP bag to the apheresis device.

At the prompt to connect anticoagulant to the apheresis device tubing set:

1. Remove the overwrap by pulling down at the notch, and remove the ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP bag.
2. Before use, perform the following checks [see *Warnings and Precautions (5)*]:
 - Check for leaks by gently squeezing the bag. If leaks are found, discard the bag
 - Ensure that the solution is the ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP and is within the expiration date
 - Inspect the solution in good light. Bags showing cloudiness, haze, or particulate matter should not be used
3. Remove the twist off port on the bag
4. Connect the bag to the apheresis device tubing set using aseptic technique and hang the solution
5. Proceed according to the apheresis device operator's manual

Drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever the solution and container permit.

3. DOSAGE FORMS AND STRENGTHS

250 mL ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP is a sterile solution in a PVC bag. Each 100 mL contains: Sodium Citrate (dihydrate) 4.0 g; Water for Injection to 100 mL, (pH adjusted with citric acid). Approximate millimoles of Sodium Citrate: 13.6.

4. CONTRAINDICATIONS

DO NOT INFUSE ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP DIRECTLY TO THE DONOR.

5. WARNINGS AND PRECAUTIONS

- Verify that the ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP has been securely attached to the anticoagulant (AC) line on the system tubing set. Use aseptic technique throughout all procedures to ensure donor safety and quality.
- Single-use container. Do not reuse. Discard any unused or partially used product.
- Rx only

6. ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the infusion of blood products to patient and return of blood containing citrate anticoagulant to donors. The recipient of the blood containing citrate should be monitored for the signs and symptoms of citrate toxicity. The signs and symptoms of citrate toxicity begin with paresthesia, a "tingling" sensation around the mouth or in the extremities, followed by severe reactions that are characterized by hypotension and possible cardiac arrhythmia. Citrate toxicity may occur more frequently in patients who are hypothermic, have impaired liver or renal function, or have low calcium levels because of an underlying disease.

8. USE IN SPECIFIC POPULATIONS

ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP has not been adequately studied in controlled clinical trials with specific populations.

11. DESCRIPTION

ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP is designed to be metered by an apheresis device in apheresis procedures, to prevent platelet activation and coagulation as blood moves throughout the extracorporeal unit (tubing set) in an apheresis procedure.

The solution is sterile and non-pyrogenic, and it contains no bacteriostatic or antimicrobial agents. Sterilized with steam.

The formulas of the active ingredients are provided in Table 1.

Table 1: Active Ingredients

Ingredients	Molecular Formula	Molecular Weight
Sodium Citrate Dihydrate	$C_6H_9Na_3O_9$	294.10
Water for Injection	H_2O	18.00

Each 100 mL of ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP contains:

Sodium Citrate (dihydrate) 4.0 g; and Water for Injection to 100 mL (pH adjusted with citric acid). Approximate millimoles of sodium citrate: 13.6.

The PVC bag is not made with natural rubber latex.

The bag contains materials that have been tested to demonstrate the suitability of the container for storing pharmaceutical solutions. The bag is nontoxic and biologically inert. The bag-solution unit is a closed system and is not dependent upon entry of external air during administration. The bag is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

12. CLINICAL PHARMACOLOGY

12.1. Mechanism of Action

ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP acts as an extracorporeal anticoagulant by binding the free calcium in the blood. Calcium is a necessary co-factor to several steps in the clotting cascade. The following ingredients are key components of the solution:

- Citric acid for pH regulation
- Sodium Citrate anticoagulant

This solution has no pharmacological effect.

16. HOW SUPPLIED/STORAGE AND HANDLING

ANTICOAGULANT SODIUM CITRATE 4% W/V SOLUTION USP is a clear solution supplied in sterile and non-pyrogenic PVC bags. The bags are packaged 30 bags per case.

SIZE	CATALOG NUMBER	NDC NUMBER
250 mL	1000782	Bag: 81839-782-01 Case: 81839-782-02

STORAGE

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° 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.

Issued: 05/2022

Manufactured By:
CSL Plasma, Inc.
155 Medical Sciences Drive
Union, SC 29379

PRINCIPAL DISPLAY PANEL - 250 mL Bag Label

ANTICOAGULANT SODIUM CITRATE
4% w/v SOLUTION, USP
250mL
NDC 81839-782-01
Product No. 1000782

Rx Only
Intended for use only with automated
apheresis devices

Each 100 mL contains:
Sodium Citrate (Dihydrate), USP 4.0g
(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° to
25°C (68° to 77°F); excursions permitted
between 15° to 30°C (59° 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.

Manufactured By:
CSL Plasma Inc.
155 Medical Sciences Dr.
Union, SC 29379 USA

Made in USA
62635V01

ANTICOAGULANT SODIUM CITRATE

4% w/v SOLUTION, USP 250mL

NDC 81839-782-01 Product No. 1000782

Rx Only
Intended for use only with automated
apheresis devices

Each 100 mL contains:
Sodium Citrate (Dihydrate), USP 4.0g
(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° to
25°C (68° to 77°F); excursions permitted
between 15° to 30°C (59° 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.

Manufactured By:
CSL Plasma Inc.
155 Medical Sciences Dr.
Union, SC 29379 USA

Made in USA 62635V01

PRINCIPAL DISPLAY PANEL - 250 mL Carton Label

Anticoagulant Sodium Citrate

4% w/v Solution, USP 250mL
NDC# 81839-782-02
30 UNITS

Rx only
Product Code: 1000782

LOT # 21X000XU

EXP. DATE YYYY MMM

Recommended Storage: Store at 20° to 25°C (68° to 77°F);
excursions permitted between 15° to 30°C (59° 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.

Manufactured By:
CSL Plasma Inc.
155 Medical Sciences Drive
Union, SC 29379

Made in USA

62635V01 000000

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

NDC# 81839-782-02

30 UNITS

Rx only

Product Code: 1000782

LOT # 21X000XU

EXP. DATE YYYY MMM

000000

Recommended Storage: Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° 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.

Manufactured By:

CSL Plasma, Inc.

155 Medical Sciences Drive
Union, SC 29379

Made in USA

62637V01 000000

ANTICOAGULANT SODIUM CITRATE

trisodium citrate dihydrate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:81839-782
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	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:81839-782-02	30 in 1 CARTON		
1	NDC:81839-782-01	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	BA125750	07/01/2022	

Labeler - CSL Plasma Inc. (942344649)

Establishment

Name	Address	ID/FEI	Business Operations
CSL Plasma Inc.		942344649	MANUFACTURE(81839-782)

Revised: 1/2024

CSL Plasma Inc.