TRICITRASOL- trisodium citrate dihydrate solution
Citra Labs LLC

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triCitrasol®

ANTICOAGULANT SODIUM CITRATE CONCENTRATE – 46.7% Trisodium Citrate
PN 6030, 30 mL
NDC 23731-6030-3

DESCRIPTION

triCitrasol® Anticoagulant Sodium Citrate Concentrate, 46.7% Trisodium Citrate, is a sterile, non-pyrogenic solution of Trisodium Citrate (Dihydrate), USP.

Each 30 mL of **concentrate** contains:

Trisodium Citrate, dihydrate, USP	14.0 grams
Water for Injection, USP	q.s.

pH adjusted with Citric Acid

pH: 6.3 – 6.6

Single patient use only, on a single occasion.

CLINICAL PHARMACOLOGY

A sodium citrate solution acts as an anticoagulant by the action of the citrate ion chelating free ionized calcium; thus, the calcium ion is unavailable to the coagulation system [1].

INDICATIONS AND USAGE

triCitrasol® Anticoagulant Sodium Citrate Concentrate, 46.7% Trisodium Citrate, is an anticoagulant used in granulocytapheresis procedures (granulocyte collection by apheresis). Just prior to performing granulocytapheresis, aseptically add 30 mL of *triCitrasol*® to 500 mL of the 6% solution of Hydroxyethyl Starch (HES), e.g. Hespan ® [2-8]. Agitate the resultant solution for 1 minute to assure a uniform concentration of anticoagulant. The resultant solution of *triCitrasol*® and 6% solution of HES contains the following concentration depending upon the volume used:

Volume of *triCitrasol*®	**Volume of HES**	**Total Volume**	**Final Concentration of *triCitrasol*®**
30 mL	500 mL (measured from HES bag)	530 mL	2.6%

30 mL	558 mL (injected directly into HES bag)	588 mL	2.4%

The *triCitrasol*®/HES solution is stable for up to 24 hours at room temperature after mixing.

Refer to the manufacturer's Operator's Manual of the apheresis medical device for the directions to perform the granulocytapheresis procedure.

CONTRAINDICATIONS

NOT FOR DIRECT INTRAVENOUS INFUSION.

WARNINGS

CONCENTRATED ANTICOAGULANT – DILUTE PRIOR TO USE.

PRECAUTIONS

General

Aseptic technique must be maintained at all times.

triCitrasol® Anticoagulant Sodium Citrate Concentrate is a clear/colorless solution. If the product shows any cloudiness or turbidity, the concentrate should be discarded.

The cap/stopper system provides a biological barrier and should be intact – discard product if system is comprised.

Information for Patients

None.

Laboratory Tests

There are no laboratory tests for the drug product at this time.

Drug Interactions

There are no adverse reactions for the addition of the product to the rouleaux agent.

Carcinogenesis, mutagenesis, impairment of fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of *triCitrasol*®.

Pregnancy

Long-term studies in animals have not been performed to evaluate the effects of *triCitrasol*® on pregnant women.

Pediatric Use

The safety and effectiveness of *triCitrasol*® in children have not been established.

ADVERSE REACTIONS

Citrate reactions or toxicity may occur with the infusion of blood products containing citrate anticoagulant [1, 9 11]. The recipient of the citrated blood product should be monitored for the signs and symptoms of citrate toxicity [1, 9 11]. 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 chills, stomach cramps, or pressure in the chest, followed by more severe reactions that are characterized by hypotension and possible cardiac arrhythmia [1, 9 11]. Citrate toxicity may occur more frequently in patients that are hypothermic [10], have impaired liver or renal function [10], or have low calcium levels because of an underlying disease [9].

OVERDOSAGE

Since the bottle of *triCitrasol*® contains only 30mL of the product, it is impossible to overdose the addition of the product to the 6% solution of HES. However, in the event of a reaction to the infusion of citrated blood products, evaluate the patient and institute appropriate corrective actions [1, 9].

DOSAGE AND ADMINISTRATION

The apheresis system will control the amount of the citrate/6% solution of HES that is added to the whole blood and the method of administration of the solution. Refer to the Operator's Manual of the apheresis medical device.

HOW SUPPLIED

triCitrasol® Anticoagulant Sodium Citrate Concentrate 46.7% Trisodium Citrate

REF	SIZE	CASE
PN 6030-25	30 mL Vial	25 Vials/Case
PN 6030-10	30 mL Vial	10 Vials/Case

It is recommended that the product be stored at ambient room temperature, 24°C (75°F); however, the product can be stored between 15°C (59°F) and 30°C (86°F). Protect from freezing and exposure to excessive heat should be minimized.

Rx ONLY

triCitrasol® is a registered trademark of Citra Labs, LLC, Braintree, MA.

Hespan ® is a registered trademark of B. Braun Medical, Inc., Irvine, CA.

REFERENCES

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Printed in USA

PRINCIPAL DISPLAY PANEL - 10 Vial Case Label

triCitrasol®

ANTICOAGULANT SODIUM CITRATE CONCENTRATE
46.7% Trisodium Citrate
PN 6030 - 30 mL
WARNING: CONCENTRATED ANTICOAGULANT
Dilute prior to use
NOT FOR DIRECT INTRAVENOUS INFUSION

THIS CARTON CONTAINS
10 Sterile Units - 30 mL each

Used with 6% Hydroxyethyl Starch 500 mL (diluent) for the Collection of Granulocytes by Apheresis. Do not use for other anticoagulant purposes. See package insert for directions for use.

Manufactured & Distributed by:
Citra Labs™
A Biomet Inc. Company.
55 Messina Drive, Braintree, MA 02184 ● USA
Phone Number: 1-800-299-3411
Fax Number: 781-848-6781

Sterile ■ Non-Pyrogenic

Composition per 30 mL of Concentrate:
Trisodium Citrate (Dihydrate), USP 14.0 g
(pH adjusted with Citric Acid)

CAUTION: Single Procedure Use - Discard Unused Portion
Do Not Use Unless Solution is Clear and Seal is intact
Store Between 15°C - 30° C (59° F - 86° F)

Rx only

Exp:

Lot:

LA6030-10B 5/15

PRINCIPAL DISPLAY PANEL - 25 Vial Case Label

***triCitrasol*®**

ANTICOAGULANT SODIUM CITRATE CONCENTRATE
46.7% Trisodium Citrate
PN 6030 - 30 mL
WARNING: CONCENTRATED ANTICOAGULANT
Dilute prior to use
NOT FOR DIRECT INTRAVENOUS INFUSION

THIS CARTON CONTAINS
25 Sterile Units - 30 mL each

Used with 6% Hydroxyethyl Starch 500 mL (diluent) for the Collection of Granulocytes by Apheresis. Do not use for other anticoagulant purposes. See package insert for directions for use.

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A Biomet Inc. Company.
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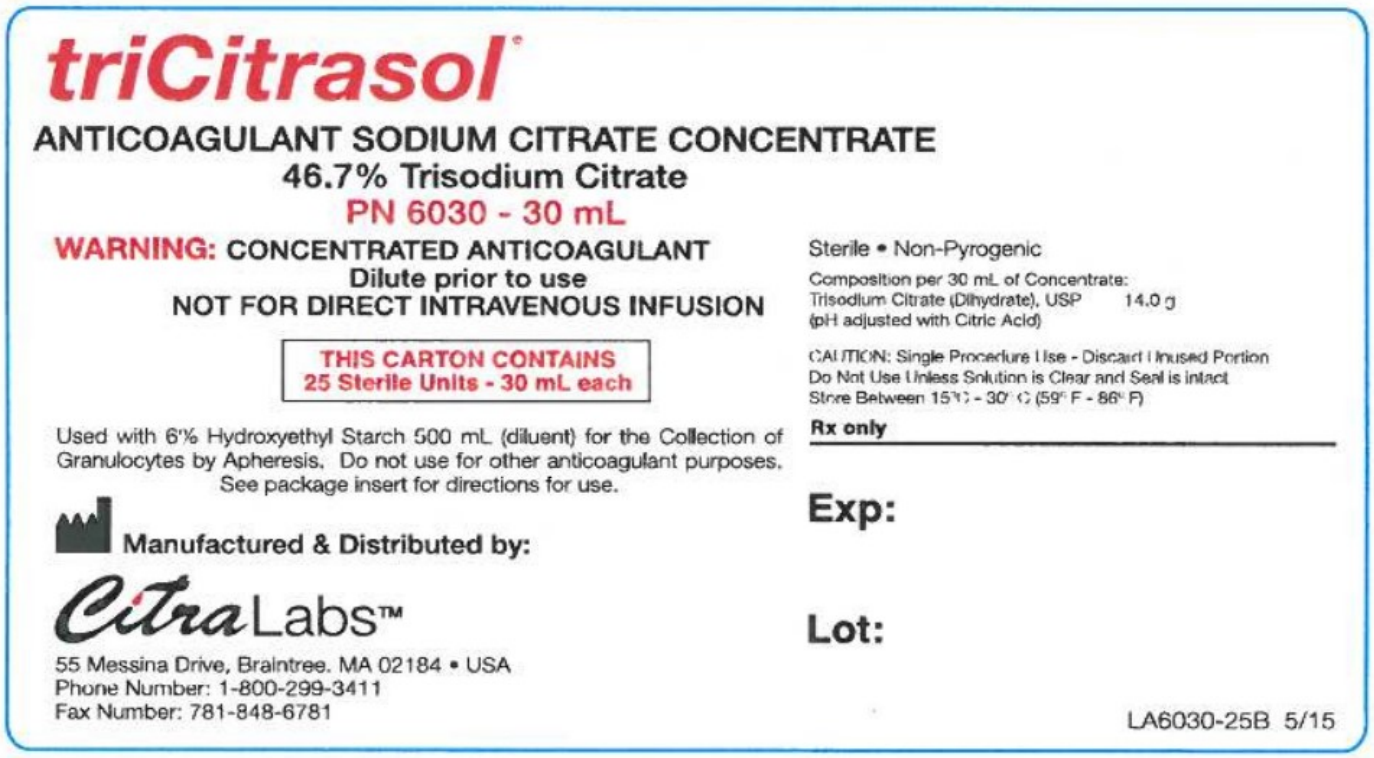
Rx only

Exp:

Lot:

LA6030-25B 5/15



TRICITRASOL

trisodium citrate dihydrate solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:23731-6030
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	14 g in 30 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:23731-6030-1	10 in 1 CASE		
1	NDC:23731-6030-3	30 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		
2	NDC:23731-6030-2	25 in 1 CASE		
2	NDC:23731-6030-3	30 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN010409	07/10/2003	

Labeler - Citra Labs LLC (962863838)

Establishment

Name	Address	ID/FEI	Business Operations
Citra Labs, LLC		962863838	MANUFACTURE(23731-6030)

Revised: 2/2023 Citra Labs LLC