

TRICITRASOL- trisodium citrate dihydrate solution

Citra Labs LLC

triCitasol®

ANTICOAGULANT SODIUM CITRATE CONCENTRATE – 46.7% Trisodium Citrate

PN 6030, 30 mL

NDC 23731-6030-3

DESCRIPTION

triCitasol® 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 system¹.

INDICATIONS AND USAGE

triCitasol® 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 *triCitasol®* 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 *triCitasol®* and 6% solution of HES contains the following concentration depending upon the volume used:

Volume of <i>triCitasol®</i>	Volume of HES	Total Volume	Final Concentration of <i>triCitasol®</i>
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 *triCitasol®*/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 hypothermic¹⁰, have impaired liver or renal function¹⁰, or have low calcium levels because of an underlying disease⁹.

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

triCitasol[®] 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

triCitasol[®] is a registered trademark of Citra Labs, LLC, Braintree, MA.

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

REFERENCES

1. Grindon, A. J., "Adverse Reactions to Whole Blood Donation and Plasmapheresis", *CRC Crit. Rev Clin. Lab. Sci.*, 17:51-75, 1982.
2. Rock, G., and McCombie, N., "Alternate Dosage Regimens for High-Molecular-Weight Hydroxyethyl Starch", *Transfusion*, 25:417-419, 1985.
3. Strauss, R. G., Hester, J. P., Vogler, W.R., Higby, D. J., Snikeris, A. C., Imig, K. M., Greazel, C., Mallard, G., Burnett, D., Gupta, S., and Hulse, J.D., "A Multicenter Trial to Document the Efficacy and Safety of a Rapidly Excreted Analog of Hydroxyethyl Starch for Leukapheresis with a Note on Steroid Stimulation of Granulocyte Donors", *Transfusion*, 26:258-264, 1986.
4. Strauss, R.G., Rohret, P.A., Randels, M. J., and Wihegarden, D. C., "Granulocyte Collection", *J. of Clin. Apheresis*, 6:241-243, 1991.
5. Lee, J.H., and Klein, H. G., "The Effect of Donor Red Cell Sedimentation Rate on Efficiency of Granulocyte Collection by Centrifugal Leukapheresis", *Transfusion*, 35:384-388, 1995.
6. Adkins, D., Ali, S. Despotis, G., Dynis, M. and Goodnough, L. T., "Granulocyte Collection Efficiency and Yield are Enhanced by the Use of a Higher Interface Offset During Apheresis of Donors Given Granulocyte-Colony-Stimulating Factor", *Transfusion*, 38:557-564, 1998.
7. Jendiroba, D. B., Lichtiger, B., Anaissie, E., Reddy, V., O'Brien, S., Kantarjian, H., and Freireich, E. J., "Evaluation and Comparison of Three Mobilization Methods for the Collection of Granulocytes". *Transfusion*, 38:722-728, 1998.
8. Leavey P. J., Thurman, G., and Anbruso, D. R., "Functional Characteristics of Neutrophils Collected and Stored After Administration of G-CSF", *Transfusion*. 40:414-419, 2000.
9. AABB Technical Manual, 14th Edition, page 590, 2001.
10. Denlinger, J.V., Nahrwold, M. L., Gibbs, P.S., and Lecky, J.H., "Hypocalcemia During Rapid Blood Transfusion in Anaesthetized Man", *Br. J. Anaesth.*, 48:995-1000, 1976.
11. Stack, G., Judge, J.V., and Snyder, E.L., "Febrile and Nonimmune Transfusion Reactions", in Principles of Transfusion Medicine, pp. 780-781, editors Rossi, E.C., Simon, T.L., Moss, G.S., and

Gould, S.A., Williams & Wilkins, Baltimore, MD, 2nd ed., 1996.

Manufactured & Distributed by: Citra Labs, LLC, 55 Messina Drive, Braintree, MA 02184 • 1-800-299-3411 or 1-781-848-2174 Fax: 1-781-848-6781

FL6030 04/13
Printed in USA

PRINCIPAL DISPLAY PANEL - 10 Vial Case Label

triCitasol[®]

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[™]

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

triCitasol

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™

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

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)	Trisodium Citrate dihydrate	0.467 g in 1 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)

Revised: 7/2015

Citra Labs LLC