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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trisodium Citrate, dihydrate, USP</td>
<td>14.0 grams</td>
</tr>
<tr>
<td>Water for Injection, USP</td>
<td>q.s.</td>
</tr>
</tbody>
</table>

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.

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®. 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:

<table>
<thead>
<tr>
<th>Volume of triCitrasol®</th>
<th>Volume of HES</th>
<th>Total Volume</th>
<th>Final Concentration of triCitrasol®</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mL</td>
<td>500 mL (measured from HES bag)</td>
<td>530 mL</td>
<td>2.6%</td>
</tr>
<tr>
<td>30 mL</td>
<td>558 mL (injected directly into HES bag)</td>
<td>588 mL</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

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. The recipient of the citrated blood product 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 chills, stomach cramps, or pressure in the chest, followed by more severe reactions that are characterized by hypotension and possible cardiac arrhythmia. Citrate toxicity may occur more frequently in patients that are hypothermic, have impaired liver or renal function, or have low calcium levels because of an underlying disease.

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.

**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

<table>
<thead>
<tr>
<th>REF</th>
<th>SIZE</th>
<th>CASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PN 6030-25</td>
<td>30 mL Vial</td>
<td>25 Vials/Case</td>
</tr>
<tr>
<td>PN 6030-10</td>
<td>30 mL Vial</td>
<td>10 Vials/Case</td>
</tr>
</tbody>
</table>

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**

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
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
TRICITRASOL
trisodium citrate dihydrate solution

Product Information

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<th>Product Type</th>
<th>Item Code (Source)</th>
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<table>
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<th>Route of Administration</th>
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<tr>
<td>EXTRACORPOREAL</td>
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Active Ingredient/Active Moiety

<table>
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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>trisodium citrate dihydrate</td>
<td>anhydrous citric acid</td>
<td>14 g in 30 mL</td>
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<table>
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<th>Packaging</th>
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### Marketing Information

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<td>NDA</td>
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### Labeler
- Citra Labs LLC (962863838)

### Establishment

<table>
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<tr>
<th>Name</th>
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<tr>
<td>Citra Labs, LLC</td>
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<td>962863838</td>
<td>manufacture(23731-6030)</td>
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Revised: 11/2019

Citra Labs LLC