**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.

**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>588 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 ANTI COAGULANT – 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**

Citrates 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 30 mL 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 action.

**DOSE 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**


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

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