

PRODUCT MONOGRAPH

Citrasate® C1150

Haemodialysis Solution, BP

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|---------------------|------------|
| Sodium Chloride | 263 g / L |
| Potassium Chloride | 3.35 g / L |
| Calcium Chloride | 7.47 g / L |
| Magnesium Chloride | 2.14 g / L |
| Citric Acid | 6.91 g / L |
| Sodium Acetate | 1.11 g / L |
| Glucose Monohydrate | 49.5 g / L |

Chief Medical Supplies Ltd.

411-19th Street S.E.

Calgary Alberta T2E 6J7

Control No.: 242792

Date of Revision:

January 14, 2021

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Citrasate® C1150

Haemodialysis Solution, BP

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

| Route of Administration | Dosage Form / Strength | Clinically Relevant Non-medical Ingredients |
|-------------------------|--|---|
| Hemodialysis | Concentrated solution Sodium Chloride 263 g / L Potassium Chloride 3.35 g / L Calcium Chloride 7.47 g / L Magnesium Chloride 2.14 g / L Citric Acid 6.91 g / L Sodium Acetate 1.11 g / L Glucose Monohydrate 49.5 g / L | None |

INDICATIONS AND CLINICAL USE

Citrasate C1150 is indicated for use as the “Acid” component of a two-component mixture use for hemodialysis treatment for patients suffering from renal insufficiency.

One part of this acid concentrate solution must be diluted with 1.72 parts of concentrated Sodium Bicarbonate solution, and 42.28 parts purified water USP to make a dialysate that is used for the hemodialysis treatment. A three-stream hemodialysis machine must mix the Bicarbonate component with an Acid component simultaneously with purified water USP to make dialysate that is used for the hemodialysis treatment.

CONTRAINDICATIONS

Citrasate C1150 is contraindicated for use:

- in patients who are hypersensitive to this drug or to any component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the Product Monograph.
- for injection or peritoneal dialysis.

WARNINGS AND PRECAUTIONS

General:

- For hemodialysis use only. Do not use for injection or peritoneal dialysis.
- Do not use alone in hemodialysis. Must be used in conjunction with a concentrated Bicarbonate Solution as recommended by the manufacturer of the hemodialysis machine.
- Do not use either concentrate or diluted solution showing precipitate, or if container is damaged, or if seal is broken.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

There is no reported adverse effect of Citrasate C1150. Citrasate is well tolerated by patients on hemodialysis and there are no known long-term adverse consequences.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

DRUG INTERACTIONS

Drug-Drug Interactions

No known drug interactions.

DOSAGE AND ADMINISTRATION

Dosing Considerations:

Preparation of Parenteral Solution:

1. Citrasate C1150 must be diluted immediately before use.
2. Volume of concentrate taken for dilution must be measured accurately.
3. Mix diluted solution thoroughly before use.
4. Verify concentration of diluted solution before use.
5. Use immediately after preparation. Discard unused Citrasate.

Recommended Dose and Dosage Adjustment:

Adults: Approximately 2.7 L of Citrasate C1150 is required for 5 hours of hemodialysis treatment at dialysate flow rate of 400 ml/minute. Each container contains sufficient concentrate to perform 3 – 5 hours hemodialysis treatment at a dialysate flow rate of 400 ml/minute.

Administration:

Citrasate C1150 is administered by the process of dialysis, using a three-stream hemodialysis machine.

Citrasate C1150 is a clear, colourless homogeneous solution of Sodium Chloride, Potassium Chloride, Calcium Chloride, Magnesium Chloride, Glucose Monohydrate, Citric Acid and Sodium Acetate. The concentration of the components in solutions after dilution 1 in 44 with sterile water USP are as follows:

| | |
|---------------|--------------|
| Sodium ion | 100.3 mmol/L |
| Potassium ion | 1 mmol/L |
| Calcium ion | 1.5 mmol/L |
| Magnesium ion | 0.5 mmol/L |
| Chloride ion | 105 mmol/L |
| Citric Acid | 0.8 mmol/L |
| Acetate | 0.3 mmol/L |
| Glucose | 5.55 mmol/L |

OVERDOSAGE

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|---|
| For management of a suspected drug overdose, contact your regional Poison Control Center. |
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Limited over-dosage experience is available. There is no reported overdose effect of Citrasate C1150. The solution should never be administered directly to patients. Over concentrated solutions are rejected by the hemodialysis machine.

ACTION AND CLINICAL PHARMACOLOGY

Citrasate solutions react with bicarbonate ions from Bicarbonate Concentrate B38 to form water and carbon dioxide.

During a normal 4 hour dialysis treatment, as a result of diffusion, the sodium, potassium, calcium and magnesium electrolytes composition of blood will equilibrate to the electrolytes composition of Citrasate C1150. Urea, creatinine, phosphate and other small molecular weight toxins will diffuse out from the blood into the diluted Citrasate C1150.

Diffusive removal of sodium during dialysis will result in the movement of water from extracellular space to the intracellular space.

Diffusive removal of potassium will result in increased frequency of cardiac arrhythmias.

STORAGE AND STABILITY

Store at room temperature (15 - 30°C). Do not freeze.

DOSAGE FORMS, COMPOSITION AND PACKAGING

How Supplied:

Citrasate C1150 is supplied in 4.5 L and 5 L polyethylene containers.

The nonmedicinal ingredient is USP grade purified water. The pH of the solution is 1.4 – 2.1. The solution tastes salty and has a citric acid odour.

The solution is non-sterile.

REFERENCES

1. Daugirdas John T., Ing Todd S., “Dialysis Solution Base”. Handbook of Dialysis – First Edition, page 32-35, Little, Brown and Company Boston/Toronto. 1988.
2. Stone John C., “Individualization of Dialysate Prescription in Chronic Hemodialysis”. Dialysis And Transplantation, Volume 23, 1994.

3. Henrich William L., “Dialysate Buffer”. Principle and Practice of Dialysis, page 8-15, Williams & Wilkins. 1994.

MORE INFORMATION

If you want more information about Citrasate C1150:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drugproduct-database.html>); or by visiting the manufacturer’s website (www.chiefmedical.com) or by calling: 1-403-207-6034.

This leaflet was prepared by Chief Medical Supplies Ltd.

Last Revised: January 14, 2021