PRODUCT MONOGRAPH

Hemosate Ultra HS4125

Haemodialysis Solution, BP

Sodium Chloride	263 g / L
Potassium Chloride	13.47 g / L
Calcium Chloride	6.24 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

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Non-medicinal Ingredients
Hemodialysis	Concentrated solution Sodium Chloride 263 g / L Potassium Chloride 13.47 g / L Calcium Chloride 6.24 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

Hemosate Ultra HS4125 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

Hemosate Ultra HS4125 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 Hemosate Ultra HS4125. Hemosate Ultra 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. Hemosate Ultra HS4125 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 Hemosate Ultra.

Recommended Dose and Dosage Adjustment:

Adults: Approximately 2.7 L of Hemosate Ultra HS4125 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:

Hemosate Ultra HS4125 is administered by the process of dialysis, using a three-stream hemodialysis machine.

Hemosate Ultra HS4125 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	4 mmol/L
Calcium ion	1.25 mmol/L
Magnesium ion	0.5 mmol/L
Chloride ion	107.5 mmol/L
Citric Acid	0.8 mmol/L
Acetate	0.3 mmol/L
Glucose	5.55 mmol/L

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Center.

Limited over-dosage experience is available. There is no reported overdose effect of Hemosate Ultra HS4125. The solution should never be administered directly to patients. Over concentrated solutions are rejected by the hemodialysis machine.

ACTION AND CLINICAL PHARMACOLOGY

Hemosate Ultra 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 Hemosate Ultra HS4125. Urea, creatinine, phosphate and other small molecular weight toxins will diffuse out from the blood into the diluted Hemosate Ultra HS4125.

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^{o}C). Do not freeze.

DOSAGE FORMS, COMPOSITION AND PACKAGING

How Supplied:

Hemosate Ultra HS4125 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 Hemosate Ultra HS4125:

- 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.

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