1.3.1.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE

HAEMOCARB ADCO (Acid concentrate).

This solution is intended to be used together with **LIQUID BICARBONATE ADCO (Bicarbonate concentrate).**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

HAEMOCARB ADCO

Sodium chloride	172,2 g
Potassium chloride	5,5 g
Calcium chloride (dihydrate)	9,5 g
Magnesium chloride (hexahydrate)	3,7 g
Glacial acetic acid	8,8 g
Water for injections	ad 1 000 ml

LIQUID BICARBONATE ADCO

Sodium bicarbonate	65,95 g
Sodium chloride	23,53 g
Water for injections	ad 1 000 ml

Final dialysate concentrations

Dialysate comprised of HAEMOCARB ADCO (Acid concentrate), LIQUID BICARBONATE ADCO and purified water mixed in the ratio 1: 1,83: 34 will contain the following nominal concentrations:

Approximate mmol per litre:

Sodium	139
Calcium	1,75
Potassium	2,0
Magnesium	0,50
Chloride	106,5
Bicarbonate	39*
Acetate	4,0

* The glacial acetic acid in the acid concentrate will neutralize 4,0 mmol/l bicarbonate. The final dialysate will have 35 mmol bicarbonate per litre.

Sugar content: Sugar free

3. PHARMACEUTICAL FORM

HAEMOCARB ADCO

Acid concentrate

A clear, colourless solution.

LIQUID BICARBONATE ADCO

Bicarbonate concentrate

A clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bicarbonate dialysis using HAEMOCARB ADCO acid concentrate and LIQUID BICARBONATE ADCO bicarbonate concentrate is indicated for the following:

Patients with acute or chronic renal failure, when nondialytic medical therapy is judged to be inadequate, and suffering from acetate intolerance or vascular instability.

4.2 Posology and method of administration

Posology

The duration of dialysis, dialyser used, amount of fluid to be removed and other details of each dialysis session should be selected and specified by the nephrologist in charge according to the individual patients' requirements at that particular stage.

Method of administration

When ready to use the machine, connect the HAEMOCARB ADCO acid concentrate acidified line 5 minutes before connecting the LIQUID BICARBONATE ADCO bicarbonate concentrate to the bicarbonate line. When dialysis is complete, disconnect the bicarbonate line 5 minutes before disconnecting the acid concentrate.

ABBA: Connect acid first, then bicarbonate - before treatment.

Disconnect bicarbonate first, then acid - after treatment.

LIQUID BICARBONATE ADCO is supplied in a single dose container. Do not use if the container is damaged or leaking. Bacterial growth may occur in concentrated liquid bicarbonate solutions. Do not use unless solution is clear. Use immediately after opening. Do not store open or partly used containers. Discard unused solution.

4.3 Contraindications

None known

4.4 Special warnings and precautions for use

Patients with high blood pressure and chronic uremia should be treated with care as the removal of large fluid volumes may result in hypotension and significantly higher plasma dopamine-b-hydroxylase activity.

4.5 Interactions with other medicines and other forms of interaction

Interaction studies have not been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy and Breastfeeding

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

a. Summary of the safety profile

Not applicable

b. Tabulated summary of adverse reactions

Though a distinct rarity, dialysis induced symptomatic hypotension may occur during and after treatments. Symptoms are dizziness, malaise, nausea and cramps accompanied by a fall in blood pressure.

If the removal of ultrafiltrate exceeds the recommended rate, hypovolemic shock with all its attendant symptoms may occur.

c. Description of selected adverse reactions

Not applicable

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

4.9 Overdose

None known.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A.34 (Others).

Dialysis solutions are solutions of electrolytes formulated in concentrations similar to those of extracellular fluid. They are used in the management of renal failure and certain forms of poisoning, they allow the selective removal of toxic substances, electrolytes and excessive body fluid from the blood. In haemodialysis, the exchange of ions between the solution and the patients blood is made across a semi-permeable membrane.

5.2 Pharmacokinetic properties

Not Applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections or Purified water (Reverse osmosis).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

SABAX HAEMOCARB: 24 months

LIQUID BICARBONATE ADCO: 12 months

Once opened, LIQUID BICARBONATE ADCO solution should be used immediately.

6.4 Special precautions for storage

Store at or below 25 °C and keep out of reach of children.

6.5 Nature and contents of container

SABAX HAEMOCARB is supplied in a 5 litre or 6 litre rectangular plastic container.

LIQUID BICARBONATE ADCO is supplied in a 5 litre or 6 litre rectangular plastic container.

6.6 Special precautions for disposal and other handling

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Critical Care (Pty) Ltd.

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Aeroton,

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8. REGISTRATION NUMBER(S)

HAEMOCARB ADCO (Acid concentrate): 29/34/0328

NA: NS2 04/34/1665

LIQUID BICARBONATE ADCO (Bicarbonate concentrate): 29/34/0329

NA: NS2 04/34/1663

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

SABAX HAEMOCARB: Date approved 09 November 1995

LIQUID BICARBONATE ADCO: Date approved 09 November 1995

10. DATE OF REVISION OF THE TEXT

Date amended: 09 February 2024