SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 95A Solution

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 127A Solution

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 139A Solution

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 192A Solution

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 196A Solution

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 380A Solution

ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 % Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1000 mL of **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW** contains:

	Acidic Bicarbonate Haemodialysis Concentrate SW 95A	Acidic Bicarbonate Haemodialysis Concentrate SW 127A	Acidic Bicarbonate Haemodialysis Concentrate SW 139A	Acidic Bicarbonate Haemodialysis Concentrate SW 192A	Acidic Bicarbonate Haemodialysis Concentrate SW 196A	Acidic Bicarbonate Haemodialysis Concentrate SW 380A
Sodium Chloride	210,69 g/L	210,68 g/L	210,68 g/L	210,68 g/L	210,68 g/L	210,68 g/L
Potassium Chloride	5,23 g/L	5,22 g/L	5,22 g/L	5,22 g/L	5,22 g/L	5,22 g/L
Calcium Chloride Dihydrate	9,02 g/L	6,43 g/L	9,01 g/L	7,72 g/L	6,43 g/L	7,72 g/L
Magnesium Chloride Hexahydrate	3,57 g/L	3,56 g/L	3,56 g/L	3,56 g/L	3,56 g/L	3,56 g/L
Glacial Acetic Acid	7,31 g/L	6,31 g/L	6,31 g/L	6,31 g/L	6,31 g/L	6,31 g/L

Glucose Monohydrate		38,5 g/L	38,5 g/L			38,5 g/L

Each 1000 mL **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** solution contains:

Sodium Bicarbonate 84,0 g

Final Dialysate Concentrations:

1 L ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and 32,775 L water of a suitable grade + 1,225 L ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 % yields a ready-to-use haemodialysis solution with the following electrolyte concentration:

	Acidic Bicarbonate Haemodialysis Concentrate SW 95A	Acidic Bicarbonate Haemodialysis Concentrate SW 127A	Acidic Bicarbonate Haemodialysis Concentrate SW 139A	Acidic Bicarbonate Haemodialysis Concentrate SW 192A	Acidic Bicarbonate Haemodialysis Concentrate SW 196A	Acidic Bicarbonate Haemodialysis Concentrate SW 380A
Sodium	138 mmol/L	138 mmol/L	138 mmol/L	138 mmol/L	138 mmol/L	138 mmol/L

Potassium	2 mmol/L	2 mmol/L	2 mmol/L	2 mmol/L	2 mmol/L	2 mmol/L
Calcium	1,75 mmol/L	1,25 mmol/L	1,75 mmol/L	1,5 mmol/L	1,25 mmol/L	1,5 mmol/L
Magnesium	0,5 mmol/L	0,5 mmol/L	0,5 mmol/L	0,5 mmol/L	0,5 mmol/L	0,5 mmol/L
Acetate	3 mmol/L	3 mmol/L	3 mmol/L	3 mmol/L	3 mmol/L	3 mmol/L
Glucose		1 g/L	1 g/L			1 g/L
Total Chlorides	109,5 mmol/L	108,5 mmol/L	109,5 mmol/L	109 mmol/L	108,5 mmol/L	109 mmol/L
Bicarbonate*	32 mmol/L	32 mmol/L	32 mmol/L	32 mmol/L	32 mmol/L	32 mmol/L
Theoretical osmolarity of the ready-to-use haemodialysis solution	287 mOsm/L	291 mOsm/L	292 mOsm/L	286 mOsm/L	285 mOsm/L	292 mOsm/L

* The **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** contains 35 mmol/L of bicarbonate. The glacial acetic acid in the **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE**'s will neutralise 3 mmol/L of bicarbonate. The final dialysate thus has 32 mmol bicarbonate per litre.

Freshly distilled water obtained under sterile conditions is the preferred medium for the dilution of bicarbonate haemodialysis concentrates. However, purified water (Aqua purificata) may also be used if it meets the microbiological requirements of <100 CFU/mL and complies with the recommendations given below. If the water is demineralised, special attention must be paid to the possible presence of pyrogens.

If purified water is used, particularly in the case of repeated haemodialysis, it is necessary to be aware of the possible presence of trace amounts of water treatment residues or chemical elements.

In particular, it is recommended that the aluminium, tin, mercury, zinc, fluoride, phosphate and sulphate levels in the water used are monitored; a maximum aluminium concentration of 10 µg/L should not be exceeded. Water used for haemodialysis should be free from unbound chloride and ozone.

Note: Drinking water is not suitable for the preparation of haemodialysis solutions.

3. PHARMACEUTICAL FORM

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE's and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE BIC 8.4 %** are clear, colourless solutions.

4. CLINICAL PARTICULARS

4.1.Therapeutic indications

The indications below apply exclusively to the ready-to-use bicarbonate haemodialysis solution prepared from alkaline and acidic bicarbonate haemodialysis concentrates diluted as directed:

- Acute renal failure
- Chronic renal failure
- Hyperhydration
- Intoxication
- Compensation of the acid-base and electrolyte balances
- Adjustment of the blood/plasma/body temperature

4.2. Posology and method of administration

Posology

The details for dialysis session, the duration of dialysis, dialyser used, rate of fluid removal, etc. must be specified by the attending nephrologist per patient, in line with the patient's condition.

Method of administration

Unless otherwise prescribed, mix alkaline and acidic bicarbonate haemodialysis concentrate with water of a suitable grade (see section 2).

The machine automatically proportions the alkaline bicarbonate, acidic concentrate and water to produce the bicarbonate dialysis fluid (ready to use solution).
Instructions for use on haemodialysis machines: Follow manufacturer's instructions according to the operating manual of the specific haemodialysis machine in use.

Notes: Do not use **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW** after the expiry date printed on the container. Use immediately after opening. Discard any surplus. Do not use if concentrate is not clear.
The concentration of the ready-to-use bicarbonate haemodialysis solution must be monitored carefully.

4.3 Contraindications

- Hyperkalaemia with the use of a potassium-containing acidic bicarbonate haemodialysis concentrate;
- Hypokalaemia with the use of a potassium-free acidic bicarbonate haemodialysis concentrate;
- Intractable coagulopathy

4.4 Special warnings and precautions for use

In patients with unstable circulation and/or unstable blood pressure, a different extracorporeal method of treatment may be indicated.

Special precautions

If the removal of ultra filtrate exceeds the recommended rate, hypovolaemic shock may occur.
Patients with high blood pressure and chronic uremia should be treated with care as the removal of large volumes may result in hypotension and significantly higher plasma dopamine-β-hydroxylate activity.

4.5 Interaction with other medicines and other forms of interaction

The effects of dialysis and filtration procedures on drug concentrations in the body can be complex.

More medicine may be removed by one dialysis technique than another. In general, medicines of low molecular weight, high water solubility, low volume of distribution, low protein binding, and high renal clearance are most extensively removed by dialysis. For example, aminoglycosides are extensively removed by dialysis procedures, and extra doses may be needed to replace losses, usually guided by serum-drug concentrations. Specific drug dosage adjustments for dialysis procedures may be used where these are known. For medicine where the effect of dialysis is unknown, it is usual to give maintenance doses after dialysis.

Dialysis-induced changes in fluids and electrolytes have the potential to alter the effects of some medicine. For example, hypokalaemia predisposes to digoxin toxicity.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

Haemodialysis treatment should be used with particular caution and under the close doctor's supervision.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

System Organ Class	Frequency	Adverse reactions
Vascular disorders	Uncommon	Hypotension and air embolism
Gastrointestinal disorders	Uncommon	Nausea and vomiting (as symptoms of hypotension).

Nervous system disorders	Uncommon	Dizziness and convulsion (as symptoms of hypotension).
Musculoskeletal, connective tissue and bone disorders	Uncommon	Muscle cramps.
Blood and the lymphatic system disorders	Uncommon	Thrombosis and haemorrhage (related to vascular access). Accelerated atherosclerosis (long-term complications in dialysed patients)
Renal and urinary disorders	Uncommon	Acquired cystic kidney diseases (long-term complications in dialysed patients).
Infection and infestation	Uncommon	Infection (related to vascular access).
Other	Uncommon	Amyloidosis (long-term complications in dialysed patients).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the '6.04 Adverse Drug Reactions Reporting Form' found under SAHPRA's publications: https://www/sahpra.org.za/Publications/Index/8

4.9 Overdose

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A. 32.11 Solutions for haemo- or peritoneal dialysis**.**

5.2. Pharmacokinetic properties

The ready-to-use bicarbonate haemodialysis solution contains electrolytes in concentrations similar to those of extracellular fluid. They are used in haemodialysis and certain forms of poisoning and 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 patient's blood is made across a synthetic semi-permeable membrane.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

	Excipient
ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE	Purified water
ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %	Purified water Sodium Edetate

6.2. Incompatibilities

Drinking water is not suitable for the preparation of haemodialysis solutions.

6.3. Shelf life

	Shelf-life
ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 95A; **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 127A;** **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 139A;**	36 months

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 380A	
ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 192A; **ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 196A**	24 months
ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %	12 months

6.4. Special precautions for storage

Store at or below 25 °C.

Do not refrigerate.

Dilute acidic and alkaline bicarbonate haemodialysis concentrates immediately before use.

6.5. Nature and contents of container

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE and **ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %** packed into 6 litre and 10 litre translucent high density polyethylene canisters and is available in the following pack sizes: 6 litre and 10 litre or 2 x 6 litre, packed in a carton.

6.6. Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

Discard any unused portion.

Do not use alkaline bicarbonate haemodialysis concentrate 8.4 % and acidic bicarbonate haemodialysis concentrate after the expiry date printed on the container.

Do not use if concentrate is not clear and colourless.

Do not use damaged containers.

Opening of the container of the alkaline bicarbonate haemodialysis concentrate can initiate bacterial growth.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER(S)

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 95A

SOUTH AFRICA: 37/34/088

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 127A

SOUTH AFRICA: 37/34/0090

ZIMBABWE: 2018/23.3.2/5584

ZAMBIA: 506/003L

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 139A

SOUTH AFRICA: 37/34/0091

ZIMBABWE: 2018/23.3.2/5582

ZAMBIA: 506/002L

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 192A

SOUTH AFRICA: 44/32.11/0489

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 196A

SOUTH AFRICA: 44/32.11/0490

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 380A

SOUTH AFRICA: 44/32.11/0491

ZIMBABWE: 2018/23.3.2/5583

ZAMBIA: 506/001L

ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %

SOUTH AFRICA: 37/34/0089

ZIMBABWE: 2018/23.3.2/5581

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 95A	23 September 2005 November 2014
ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 127A	7 April 2006 December 2015
ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 139A	7 April 2006 December 2015
ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 192A	15 August 2013 November 2014
ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 196A	15 August 2013 November 2014
ACIDIC BICARBONATE HAEMODIALYSIS CONCENTRATE SW 380A	7 April 2006 December 2015

ALKALINE BICARBONATE HAEMODIALYSIS CONCENTRATE 8.4 %	23 September 2005 October 2015

10. DATE OF REVISION OF THE TEXT

02 November 2021