

Hemodialysis Bicarbonate

Instruction for Use

Manufacturer has been granted certificate of ISO 13485
Performed standard is ISO 23500-4

1. Suitable Machine

The product is accommodated for Baxter, Gambro, Nikkiso, B.Braun, Bellco, Hosal, Nipro, Toray, Asahi hemodialysis machine with bicarbonate cartridge holder.

2. Components

Sodium Bicarbonate

3. Characteristics

This product is solid powder.

4. Indication for use

This product should be used together with hemodialysis acid solution or hemodialysis acid powder for hemodialysis or hemofiltration treatment. It is applicable to all dialysis patients.

5. Recommended usage method

- Waggle the product gently to have sodium bicarbonate loose. Open the upper protective cover and lower protective cover of the cartridge, then fix them to the specific connecting site of the Dialysis machine.
- Meanwhile prepare the acid solution in accordance with the instruction for use of acid solution
- Assure the connection is tight. Then conduct following operation in accordance with the instruction manual of the Dialysis machine and under the supervision of a physician or qualified personnel.
- Take the cartridge down from the Dialysis machine when the dialysis treatment is finished and discard it to the designated collection container.

6. Technical Indicators

84g of Sodium Bicarbonate can be dissolved in 1L of water to make a saturated concentrate solution:

a) Pyrogen

Bacterial Endotoxin should be no more than 0.5EU/mL;

b) PH value

The value should be maintained in the range 7.0-7.8;

c) Microbial limits

Total bacterial count should be no more than 100 CFU/mL.

7. Composition and mode of the alkaline bicarbonate hemodialysis concentrate

1000ml of the concentrate contains:

Sodium bicarbonate 100g
Equivalent to: Na^+ 1190mmol
 HCO_3^- 1190mmol

Sufficient for a dialysis session lasting approx. 4-6 hours based on a dialysate flow of 500 ml/min and a sodium bicarbonate concentration of 35mmol/L.

8. Precautions in use

- This product should be used under the supervision of a physician or adequately trained personnel.
- This product is intended to be used with dialysis machine. Keep the cartridge tightly sealed until it is connected to the dialysis machine.
- Do not use this product if it expires or its pouch is damaged.
- This product is for single use only and reuse is strictly prohibited. Reuse or reprocessing of this product may lead to adverse patient reactions and/or device failure. Discard any residues after treatment in accordance with local regulations.
- For hemodialfiltration application (Online HDF procedure), special attention should be paid to the water quality in order to meet the requirements in the applicable standards and/or the European Pharmacopoeia for hemodiafiltration solutions.
- It is only used in combination with acid concentrate for hemodialysis in the given dilution according to a physician prescription. Otherwise it may cause danger to patient.
- Bacterial growth can occur when using bicarbonate concentrate.
- Overmixing bicarbonate concentrate is not allowed.

- If abnormal conditions arise during the dialysis, such as leakage, foreign matter, etc., proper measures shall be taken according to doctor's advice.
- If serious incident occurs, please inform the manufacturer or local competent authority.
- There may be 2% tolerance between the actual weight and the weight on the label.
- Please refer to the actual labeling for model, shelf life, batch code, weight, etc.

9. Contraindications

Hyperkalaemia (only for hemodialysis concentrates yielding a potassium concentration in the ready-to-use dialysis fluid of 4mmol/L or higher), hypokalaemia (only for hemodialysis concentrates yielding a potassium concentration in the ready-to-use dialysis fluid of 3mmol/L or lower). Potential adverse effects of rapid plasma potassium concentration changes should be considered when prescribing a patient's dialysis fluid potassium concentration. Uncontrollable coagulation anomalies.


















10. Storage

Please avoid crash or exposure to rain, snow or direct sunlight during transportation. Store it in 0°C~40°C, well-ventilated indoor place with relative humidity no more than 80%, without corrosive gas. Store away from chemicals and moist articles.

11. After sales service

Please keep the original packaging for any investigation on product quality.

12. Symbol

	Do not re-use		Manufacturer
	Date of manufacture		Use-by date
	Batch code		Keep dry
	Catalogue number		Keep away from sunlight
	Do not use if package is damaged		Handle with care
	Caution		Temperature limit
	Consult instructions for use		Authorized representative in the European Community
	Polypropylene		CE marking
	This end up		

 <EU Representative>


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 Keep this Instruction for use until all of the products in this carton are used up.

Date: 2023-05-05

Made in Malaysia