

## **BiCart Select combi-pak Package Leaflet**

### **DESCRIPTION**

BiCart Select® combi-pak contains a BiCart® cartridge and a SelectCart® cartridge. The SelectCart cartridge is a polypropylene cartridge containing dry sodium chloride which enables on-line preparation of a liquid sodium chloride solution used in a bicarbonate-based dialysis fluid.

When the SelectCart cartridge is attached to the holder, water is drawn by the dialysis machine through the cartridge, producing a saturated solution of sodium chloride. This solution is proportioned in the dialysis machine.

The BiCart cartridge is a polypropylene cartridge containing dry sodium hydrogen carbonate which enables on-line preparation of a liquid sodium hydrogen carbonate solution used in a bicarbonate-based dialysis fluid.

When the BiCart cartridge is attached to the holder, water is drawn by the dialysis machine through the cartridge, producing a saturated solution of sodium hydrogen carbonate. This solution is proportioned in the dialysis machine. The dialysis machine mixes the sodium chloride solution together with the A-component concentrate and the sodium hydrogen carbonate solution to produce a bicarbonate-based dialysis fluid.

In some rare cases the bicarbonate powder may contain discoloured particles or powder being slightly discoloured when exposed to water. These discolorations originate from the raw materials used during the manufacturing process of the sodium hydrogen carbonate powder. The safety and efficacy of the BiCart products are not affected by these discolorations. The powders and the liquid solution obtained from BiCart Select combi-pak meet the demands of the European Pharmacopoeia.

### **INDICATIONS**

To be used in a bicarbonate dialysis treatment of patient suffering from acute renal failure, chronic renal failure or acute intoxication with dialysable substances.

#### ***Intended use***

BiCart Select combi-pak is intended to be used for on-line preparation of haemodialysis, haemodiafiltration or haemofiltration fluids on compatible Gambro dialysis systems. BiCart Select combi-pak must always be used together with a suitable A-component concentrate.

### **SPECIFICATION**

#### ***Contents***

Each BiCart cartridge contains sodium hydrogen carbonate powder (in compliance with Ph. Eur.).

Each SelectCart cartridge contains sodium chloride powder (in compliance with Ph. Eur.).

#### ***Capacity***

At a machine setting of 140 mmol/L sodium and 34 mmol/L bicarbonate and together with a suitable A-component concentrate, as specified below, 32 litres of dialysis fluid can be produced per 100 grams of bicarbonate powder. 16.6 litres of dialysis fluid can be produced per 100 grams of sodium chloride.

***Requirements for the A-component concentrate***

The acid concentrate must be designed for use with a pure sodium chloride concentrate and a pure sodium hydrogen carbonate concentrate. It must also be suitable for a dilution ratio as recommended by the manufacturer of the dialysis machine to obtain the final dialysis fluid composition.

As an example, when the SelectBag® One AX250G concentrate is mixed with a dilution ratio of 1:200, this yields the following in mmol/L:

Potassium	2	Chloride	6
Calcium	1.5	Acetate	3
Magnesium	0.5	Glucose	5.55

Together with the sodium chloride concentrate and the sodium hydrogen carbonate concentrate from the BiCart Select combi-pak, the final dialysis fluid will have a sodium level of 140 mmol/L and a bicarbonate level of 34 mmol/L, at default machine setting.

However, if the sodium and/or bicarbonate set values on the machine are changed, then these concentration levels will be modified. The potassium, calcium and magnesium levels will not be altered.

***Requirements for water***

Dialysis machine inlet water: Inlet water quality must comply with local regulations and if no such regulations are available follow ISO 13959.

**CAUTIONS**

The information in this leaflet must be carefully read and understood before using the products.

Do not refill the BiCart or the SelectCart cartridges.

The products must only be used with dialysis machines which are specially adapted for receiving the cartridges.

This leaflet must always be used together with the Operator’s manual of the corresponding dialysis machine which describes the handling instructions in detail.

The operation of the specially adapted dialysis machine is restricted to persons who are trained in dialysis and who are completely familiar with the operating instructions stated in the Operator’s manual of the corresponding dialysis machine and in this leaflet.

The concentrates in BiCart Select combi-pak must be used within 24 hours after being primed.

This product is for single use only. Any unused solution to be discarded.

### **WARNINGS**

DO NOT use the cartridges if any damage is found or suspected.

DO NOT use if cap is missing.

DO NOT use any other type of A-component concentrate than specified under section SPECIFICATION.

DO NOT initiate dialysis without having followed the instructions in the Operator's manual of the corresponding dialysis machine regarding any recommended tests to verify the proper composition of the dialysis fluid.

DO NOT perform any unauthorized modifications or alterations to the products or to the dialysis machine as this may result in a malfunction or have other serious consequences on the safe operation of the dialysis treatment.

### **CONTRAINDICATIONS**

There are no absolute contraindications for bicarbonate dialysis.

BiCart Select combi-pak must be used only on the direction of a physician who has evaluated all the pertinent features of the products in relation to the individual patient.

### **ADVERSE REACTIONS**

Some undesirable effects related to dialysis can occur, for instance hypotension, nausea, vomiting and cramps.

### **HANDLING INSTRUCTIONS**

Please refer to the Operator's manual of the corresponding dialysis machine.

### **NOTE FOR BEST PERFORMANCE**

For best performance:

1. Keep the BiCart cartridge between 20° C and 25° C (68° F and 77° F) for 3-4 hours before use.
2. A) **Gently shake** the BiCart and SelectCart cartridges to release any caking of the powder so it is free flowing before use.

B) If caking is still present, it is possible to attach the SelectCart cartridge with the **wider end downwards** (upside down), which will further reduce the probability for conductivity alarms.

### **STORAGE AND SHELF LIFE**

#### ***Storage***

Store below 40°C (104°F)

#### ***Shelf life***

See the expiry date stated on the product label

### **WARRANTY AND LIMITATIONS OF LIABILITY**

a) The manufacturer warrants that BiCart Select combi-pak has been manufactured in accordance with their specifications and in compliance with Good Manufacturing Practices, other applicable

industry standards and regulatory requirements. If provided with the lot number of the defective product(s), the manufacturer will by replacement only, remedy manufacturing defects in the product(s) becoming apparent within six (6) months from the date of delivery to the customer.

b) The warranty under paragraph a) above is in lieu of, and to the exclusion of, any other warranty, whether written or oral, expressed or implied, statutory or otherwise and there are no warranties or merchantability, fitness for a particular purpose or other warranties, which extended beyond those described in paragraph a) above. The remedy set out above for manufacturing defects is the sole remedy available to any person due to defects in the product(s) and the manufacturer shall not be liable for any consequential or incidental loss, damage, injury or expense arising directly or indirectly from the use of the product(s), whether as a result of any defect therein or otherwise.

c) The manufacturer shall not be liable for any misuse, improper handling, non-compliance with warnings and instructions, damage arising from events after the manufacturer's release of the product(s), failure or omission to inspect the product(s) before use in order to insure that the product(s) are in proper condition, or any warranty given by independent distributors or dealers.

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