

## Field Safety Notice

### Fresenius Medical Care HD Concentrates

Our ref: FSN201809HD

Date: 19<sup>th</sup> September 2018

T +65 6837 3113  
F +65 6837 2112

Affected article number:

AP00250

Affected product name:

Acid Concentrate for Bicarbonate Haemodialysis F-A-21.5-G-34-5

Affected batch number:

MA09180529

Dear customer,

During the continuous monitoring of our HD concentrates in the market, we became aware of incorrect product label used on one single batch listed above.

Based on the investigation, incorrect product labels with the wrong article number were used during production of HD Part A concentrates which may impact the prescribed HD treatment. See the illustrations below:

#### Correct carton label on box



**ACID CONCENTRATE FOR  
BICARBONATE HAEMODIALYSIS**  
F-A-21.5-G-34-5 1+34 5L

<b>K<sup>+</sup></b>	<b>2.0 mmol/l</b>
<b>Ca<sup>++</sup></b>	<b>1.5 mmol/l</b>
<b>Gluc.</b>	<b>10.0 mmol/l</b>

**Description:**  
A clear, colourless solution with the odour of Acetic Acid

**Instructions for Use:**  
Part A should not be used alone  
Part A is for use with Haemodialysis machines capable of mixing Part A with Part B (or Sodium Bicarbonate) and Purified Water in the following ratio:

Part A	1 part
Part B	1.225 parts
Water, Purified B.P.	32.775 parts

**Dilute immediately before use.**  
Do not use Part A if any solid particles are present, if the seal is broken or if the solution is not clear.  
Discard unused portion.  
Not for injection.  
Do not use damaged containers.  
Always check the composition of the ready-to-use haemodialysis solution.

**Each 1 litre of Part A contains:**

Sodium Chloride B.P.	214.8 g
Potassium Chloride B.P.	5.2 g
Calcium Chloride 2H <sub>2</sub> O B.P.	7.7 g
Magnesium Chloride 6H <sub>2</sub> O B.P.	3.6 g
Glacial Acetic Acid B.P.	8.4 g
Glucose B.P.	69.4 g

**Millimoles per litre after mixing with Part B and dilution with Purified Water**

Sodium	140.0 mmol/l
Potassium	2.0 mmol/l
Calcium	1.5 mmol/l
Magnesium	0.5 mmol/l
Chloride	111.0 mmol/l
Acetate	4.0 mmol/l
Bicarbonate	31.0 mmol/l
Glucose	10.0 mmol/l

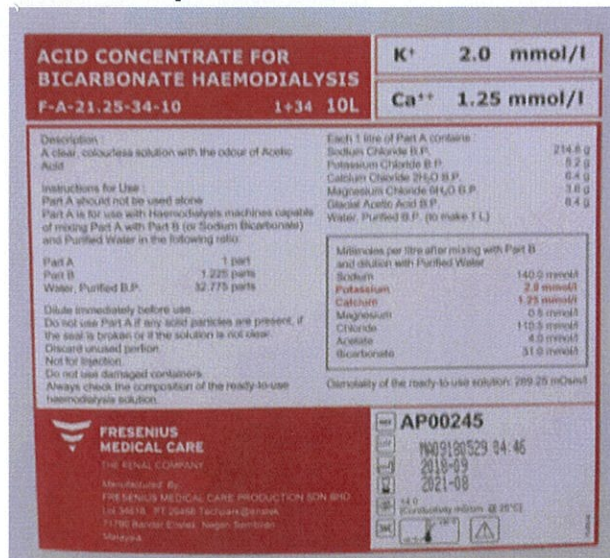
Osmolality of the ready-to-use solution: 300.00 mOsm/l

**FRESENIUS MEDICAL CARE**  
THE RENAL COMPANY  
Manufactured By:  
FRESENIUS MEDICAL CARE PRODUCTION SON BHD  
Lot 34518, PT 20460, Tembaku, Seremban  
71750 Bandar Enstek, Negeri Sembilan  
Malaysia

**AP00250**  
MA09180529 04:45  
2018-09  
2021-08

14.0 (Conductivity mS/cm @ 25°C)

#### Incorrect product label on canister



**ACID CONCENTRATE FOR  
BICARBONATE HAEMODIALYSIS**  
F-A-21.25-G-34-10 1+34 10L

<b>K<sup>+</sup></b>	<b>2.0 mmol/l</b>
<b>Ca<sup>++</sup></b>	<b>1.25 mmol/l</b>

**Description:**  
A clear, colourless solution with the odour of Acetic Acid

**Instructions for Use:**  
Part A should not be used alone  
Part A is for use with Haemodialysis machines capable of mixing Part A with Part B (or Sodium Bicarbonate) and Purified Water in the following ratio:

Part A	1 part
Part B	1.225 parts
Water, Purified B.P.	32.775 parts

**Dilute immediately before use.**  
Do not use Part A if any solid particles are present, if the seal is broken or if the solution is not clear.  
Discard unused portion.  
Not for injection.  
Do not use damaged containers.  
Always check the composition of the ready-to-use haemodialysis solution.

**Each 1 litre of Part A contains:**

Sodium Chloride B.P.	214.8 g
Potassium Chloride B.P.	5.2 g
Calcium Chloride 2H <sub>2</sub> O B.P.	6.4 g
Magnesium Chloride 6H <sub>2</sub> O B.P.	1.6 g
Glacial Acetic Acid B.P.	8.4 g

**Millimoles per litre after mixing with Part B and dilution with Purified Water**

Sodium	140.0 mmol/l
Potassium	2.0 mmol/l
Calcium	1.25 mmol/l
Magnesium	0.5 mmol/l
Chloride	110.5 mmol/l
Acetate	4.0 mmol/l
Bicarbonate	31.0 mmol/l

Osmolality of the ready-to-use solution: 289.25 mOsm/l

**FRESENIUS MEDICAL CARE**  
THE RENAL COMPANY  
Manufactured By:  
FRESENIUS MEDICAL CARE PRODUCTION SON BHD  
Lot 34518, PT 20460, Tembaku, Seremban  
71750 Bandar Enstek, Negeri Sembilan  
Malaysia

**AP00245**  
MA09180529 04:46  
2018-09  
2021-08

14.0 (Conductivity mS/cm @ 25°C)

**Required actions:**

- 1) In order to avoid any potential risk, we ask you to immediately stop using the affected product batch MA09180529.
- 2) Please provide this notice to all those who need to be aware of it within your organization.
- 3) Please complete the attached acknowledgement receipt and we will collect it during exchange of the affected products.

We sincerely apologize for the inconvenience and we will provide you with a replacement as soon as possible. You will be contacted by your local Fresenius Medical Care representative to organize the exchange.

In case of any further questions please do not hesitate to contact:

Name: Shirley Ng

Telephone: [REDACTED]

e-mail: [REDACTED]

Sincerely yours,

[REDACTED]

**Anbu Srinivasan**



Associate Director, Projects, South Asia Pacific

Cc: Chairman Medical Board and relevant Head of Departments





From:

<b>Company name (Distributor/ Hospital/ Clinic)</b>			
<b>Position</b>			
<b>Name (print)</b>			
<b>Email</b>		<b>Tel no.</b>	
<b>Signature</b>		<b>Date</b>	

Part A: I acknowledge receipt of **Field Safety Notice – Fresenius Medical Care HD concentrates**, date **19Sept2018** (Our ref: FSN201809HD)

Part B: Reconciliation of affected products for return

Article number	Batch number	Quantity
AP00250	MA09180529	