



**FRESENIUS
MEDICAL CARE**

Field Safety Notice

Fresenius Medical Care HD concentrates

Date: 27 Apr 2018

Affected article number:

AP00250

Affected product name:

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

Affected batch number:

MA02180080

Dear customer,

During the continuous monitoring of our HD concentrates on 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

The image shows the correct carton label for AP00250. The label is red and white. It contains the following information:

- ACID CONCENTRATE FOR BICARBONATE HAEMODIALYSIS**
- F-A-21.5-G-34-5**
- 1+34 5L**
- K⁺ 2.0 mmol/l**
- Ca⁺⁺ 1.5 mmol/l**
- Gluc. 10.0 mmol/l**
- 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 2H₂O B.P. 7.7 g
Magnesium Chloride 6H₂O B.P. 3.6 g
Glacial Acetic Acid B.P. 8.4 g
Glucose B.P. 69.4 g
Water, Purified B.P. (to make 1 L)
- 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 34618, PT 29468, Tekongpark@Senas
71760 Bandar Enstek, Negeri Sembilan
Malaysia.
- AP00250**
MA02180080 10:59
2018-02
2021-01
14.0 Conductivity mS/cm @ 25°C

Incorrect product label on canister

The image shows an incorrect product label for AP00246. The label is red and white. It contains the following information:

- ACID CONCENTRATE FOR BICARBONATE HAEMODIALYSIS**
- F-A-21.0-34-10**
- 1+34 10L**
- K⁺ 2.0 mmol/l**
- Ca⁺⁺ 1.0 mmol/l**
- 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 2H₂O B.P. 7.7 g
Magnesium Chloride 6H₂O B.P. 3.6 g
Glacial Acetic Acid B.P. 8.4 g
Water, Purified B.P. (to make 1 L)
- Millimoles per litre after mixing with Part B and dilution with Purified Water:**
Sodium 140.0 mmol/l
Potassium 2.0 mmol/l
Calcium 1.0 mmol/l
Magnesium 0.5 mmol/l
Chloride 110.0 mmol/l
Acetate 4.0 mmol/l
Bicarbonate 31.0 mmol/l
- Osmolality of the ready-to-use solution: 288.50 mOsm/l**
- FRESENIUS MEDICAL CARE**
THE RENAL COMPANY
Manufactured By:
FRESENIUS MEDICAL CARE PRODUCTION SON BHD
Lot 34618, PT 29468, Tekongpark@Senas
71760 Bandar Enstek, Negeri Sembilan
Malaysia.
- AP00246**
MA02180080 10:49
2018-02
2021-01
14.0 Conductivity mS/cm @ 25°C

cc: Chairman Medical Board and relevant Head of Departments



**FRESENIUS
MEDICAL CARE**

In order to avoid any potential risk, we ask you to immediately stop using the affected product batch MA02180080.

Please provide this notice to all those who need to be aware of it within your organization.

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: Sunny Peh

Telephone: 91170023

e-mail: sunny.peh@fmc-asia.com

Sincerely yours,

A large black rectangular box redacting the signature of Anthony Tann.

Anthony Tann

Managing Director,
Fresenius Medical Care (Singapore) Pte Ltd

cc: Chairman Medical Board and relevant Head of Departments