

1<sup>st</sup> January 2022

### DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

# Hemosol B0 Solutions for haemodialysis/haemofiltration: supply of non-UK labelled batches during the Covid-19 Pandemic

Dear Healthcare Professional,

## **Summary:**

To ensure continuity in supply, Baxter Healthcare Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply multi-lingual packs intended for the French market.

| Product Name<br>and MA Number | Active<br>ingredients   | UK<br>Product<br>Code | Replacemen<br>t<br>Product<br>Code | Labelling<br>Languag<br>e         | Batch<br>Numbers                         |
|-------------------------------|---|-----------------------|------------------------------------|-----------------------------------|--|
| Hemosol B0<br>PL00116/0702    | Lactic acid,<br>sodium chloride,<br>sodium hydrogen<br>carbonate,<br>calcium chloride,<br>magnesium<br>chloride | 114229                | 112084                             | French,<br>Dutch<br>and<br>German | 21G2805<br>21G2807<br>21J2109<br>21J2110 |

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

Please note the following:

- The replacement products are identical to product you will have already been using. The bags are fully compatible with the continuous renal replacement therapy (CRRT) systems on which you currently use Hemosol BO.
- The only difference is the languages of the product information. A comparison of the labelling is provided as an annex to this letter. The labels have key similarities to those of the UK approved product:
  - The product name is the same "Hemosol BO".
  - $\circ~$  The main ink colour used on the primary labels and cartons are the same blue as UK Hemosol BO
  - $\circ$   $\,$  The labelling format for presentation of ingredients amounts, chemical formula etc.



 Please ensure the UK Summary of Product Characteristics and package leaflet for Hemosol BO are followed. Both documents can be found on the Electronic Medicines Compendium at the following link: <u>www.medicines.org.uk/emc/product/2136</u>

Alternatively, copies of the Summary of Product Characteristics and package leaflet can be obtained from Baxter Medical Information, details below. Copies of the UK labelling can also be provided.

#### Do you need to do anything different when it comes to placing an order?

No, you order as you always would, using the <u>normal product code</u>. The substitution will be done behind-the-scenes by Baxter Customer Services, once we receive your order. You just need to make sure you communicate amongst your staff, so that they aware that the product code they receive on the ICU, may be different to what they normally expect.

You will be charged the same as for your normal product code.

#### Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <u>https://yellowcard.mhra.gov.uk/</u>, the free Yellow Card app available from the <u>Apple App Store</u> or <u>Google Play Store</u>, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Adverse Events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on 01635 206360, or by email to <u>vigilanceuk@baxter.com</u>.

Any drug product quality complaints (including suspected defective medicines) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team on 01604 704603, or by email to <u>UK SHS QA Complaints@baxter.com</u>.

#### Company contact point

If you have any questions about this letter or require more information about Hemosol B0, please contact Baxter Medical Information on 01635 206345 or email <u>medinfo\_uki@baxter.com</u>.

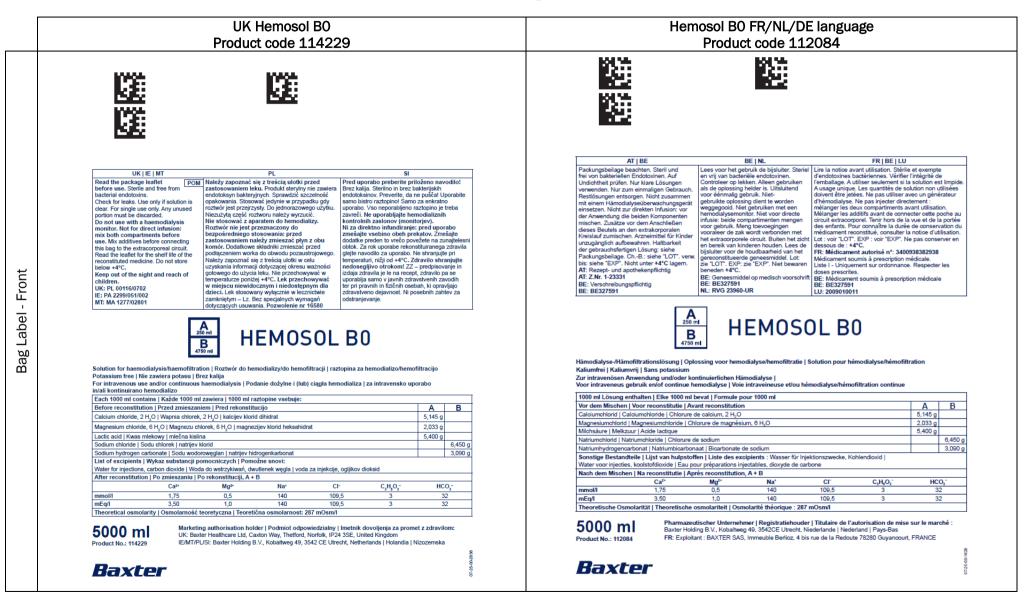
Yours faithfully

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Andrew Warburton Business Unit Head – Acute Therapies Baxter UK and Ireland

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Comparison Table of product labelling - UK vs Imported product



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