1st 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 and MA Number	Active ingredients	UK Product Code	Replacement Product Code	Labelling Language	Batch Numbers
Hemosol B0 PL00116/0702	Lactic acid, sodium chloride, sodium hydrogen carbonate, calcium chloride, magnesium chloride	114229	112084	French, Dutch and German	21G2805 21G2807 21J2109 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 B0.

- 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 B0”.
    - The main ink colour used on the primary labels and cartons are the same blue as UK Hemosol B0
    - The labelling format for presentation of ingredients amounts, chemical formula etc.

Baxter Healthcare Ltd
Caxton Way / Thetford / Norfolk / IP24 3SE / Great Britain
T 01842 767000 **F** 01842 767099
Registered Office: Caxton Way / Thetford / Norfolk / IP24 3SE Registered in England No. 461365

- Please ensure the UK Summary of Product Characteristics and package leaflet for Hemosol B0 are followed. Both documents can be found on the Electronic Medicines Compendium at the following link: www.medicines.org.uk/emc/product/2136

  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 normal product code. 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 https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, 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 vigilanceuk@baxter.com.

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 UK_SHS_QA_Complaints@baxter.com.

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 medinfo_uki@baxter.com.

Yours faithfully

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

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Comparison Table of product labelling - UK vs Imported product

Bag Label - Front

UK Hemosol B0
Product code 114229

UK | IE | MT	PL	SI
Read the package leaflet before use. Sterile and free from bacterial endotoxins. Check for leaks. Use only if solution is clear. For single use only. Any unused portion must be discarded. **Do not use with a haemodialysis monitor. Not for direct infusion: mix both compartments before use.** Mix additives before connecting this bag to the extracorporeal circuit. Read the leaflet for the shelf life of the reconstituted medicine. Do not store below +4°C. **Keep out of the sight and reach of children.** **UK: PL 00116/0702** **IE: PA 2299/051/002** **MT: MA 1277/02801** POM	**Należy zapoznać się z treścią ulotki przed zastosowaniem leku.** Produkt sterylny nie zawiera endotoksyn bakteryjnych. Sprawdzić szczelność opakowania. Stosować jedynie w przypadku gdy roztwór jest przejrzysty. Do jednorazowego użytku. Niezużytą część roztworu należy wyrzucić. **Nie stosować z aparatem do hemodializy. Roztwór nie jest przeznaczony do bezpośredniego stosowania: przed zastosowaniem należy zmieszać płyn z obu komór.** Dodatkowe składniki zmieszać przed podłączeniem worka do obwodu pozaustrojowego. Należy zapoznać się z treścią ulotki w celu uzyskania informacji dotyczącej okresu ważności gotowego do użycia leku. Nie przechowywać w temperaturze poniżej +4°C. **Lek przechowywać w miejscu niewidocznym i niedostępnym dla dzieci.** Lek stosowany wyłącznie w lecznictwie zamkniętym – Lz. Bez specjalnych wymagań dotyczących usuwania. **Pozwolenie nr 16580**	**Pred uporabo preberite priloženo navodilo!** Brez kalija. Sterilno in brez bakterijskih endotoksinov. Preverite, da ne puščal Uporabite samo bistro raztopino! Samo za enkratno uporabo. Vso neporabljeno raztopino je treba zavreči. **Ne uporabljajte hemodializnih kontrolnih zaslonov (monitorjev). Ni za direktno infundiranje: pred uporabo zmešajte vsebino obeh prekatov.** Zmešajte dodatke preden to vrečo povežete na zunajtelesni obtok. Za rok uporabe rekonstituiranega zdravila glejte navodilo za uporabo. Ne shranjujte pri temperaturi, nižji od +4°C. **Zdravilo shranjujte nedosegljivo otrokom!** ZZ – predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v javnih zdravstvenih zavodih ter pri pravnih in fizičnih osebah, ki opravljajo zdravstveno dejavnost. Ni posebnih zahtev za odstranjevanje.

A 250 ml
B 4750 ml

HEMOSOL B0

Solution for haemodialysis/haemofiltration | Roztwór do hemodializy/do hemofiltracji | raztopina za hemodializo/hemofiltracijo
Potassium free | Nie zawiera potasu | Brez kalija
For intravenous use and/or continuous haemodialysis | Podanie dożylne i (lub) ciągła hemodializa | za intravensko uporabo in/ali kontinuirano hemodializo

Each 1000 ml contains | Każde 1000 ml zawiera | 1000 ml raztopine vsebuje:		
Before reconstitution | Przed zmieszaniem | Pred rekonstitucijo	**A**	**B**
Calcium chloride, 2 H_2O | Wapnia chlorek, 2 H_2O | kalcijev klorid dihidrat	5,145 g	
Magnesium chloride, 6 H_2O | Magnezu chlorek, 6 H_2O | magnezijev klorid heksahidrat	2,033 g	
Lactic acid | Kwas mlekowy | mlečna kislina	5,400 g	
Sodium chloride | Sodu chlorek | natrijev klorid		6,450 g
Sodium hydrogen carbonate | Sodu wodorowęglan | natrijev hidrogenkarbonat		3,090 g
List of excipients | Wykaz substancji pomocniczych | Pomožne snovi: Water for injections, carbon dioxide | Woda do wstrzykiwań, dwutlenek węgla | voda za injekcije, ogljikov dioksid		
After reconstitution | Po zmieszaniu | Po rekonstituciji, A + B		

	Ca^{2+}	Mg^{2+}	Na^+	Cl^-	$C_3H_5O_3^-$	HCO_3^-
mmol/l	1,75	0,5	140	109,5	3	32
mEq/l	3,50	1,0	140	109,5	3	32

Theoretical osmolarity | Osmolarność teoretyczna | Teoretična osmolarnost: 287 mOsm/l

5000 ml
Product No.: 114229

Marketing authorisation holder | Podmiot odpowiedzialny | Imetnik dovoljenja za promet z zdravilom:
UK: Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE, United Kingdom
IE/MT/PL/SI: Baxter Holding B.V., Kobaltweg 49, 3542 CE Utrecht, Netherlands | Holandia | Nizozemska

Baxter

07-25-00-2836

Hemosol B0 FR/NL/DE language
Product code 112084

AT | BE	BE | NL	FR | BE | LU
Packungsbeilage beachten. Steril und frei von bakteriellen Endotoxinen. Auf Undichtheit prüfen. Nur klare Lösungen verwenden. Nur zum einmaligen Gebrauch. Restlösungen entsorgen. Nicht zusammen mit einem Hämodialyseüberwachungsgerät einsetzen. Nicht zur direkten Infusion: vor der Anwendung die beiden Komponenten mischen. Zusätze vor dem Anschließen dieses Beutels an den extrakorporalen Kreislauf zumischen. Arzneimittel für Kinder unzugänglich aufbewahren. Haltbarkeit der gebrauchsfertigen Lösung: siehe Packungsbeilage. Ch.-B.: siehe "LOT". verw. bis: siehe "EXP". Nicht unter **+4°C** lagern. **AT:** Rezept- und apothekenpflichtig **AT: Z.Nr. 1-23331** **BE:** Verschreibungspflichtig **BE: BE327591**	Lees voor het gebruik de bijsluiter. Steriel en vrij van bacteriële endotoxinen. Controleer op lekken. Alleen gebruiken als de oplossing helder is. Uitsluitend voor éénmalig gebruik. Niet-gebruikte oplossing dient te worden weggegooid. Niet gebruiken met een hemodialysemonitor. Niet voor directe infusie: beide compartimenten mengen voor gebruik. Meng toevoegingen vooraleer de zak wordt verbonden met het extracorporele circuit. Buiten het zicht en bereik van kinderen houden. Lees de bijsluiter voor de houdbaarheid van het gereconstitueerde geneesmiddel. Lot: zie "LOT". EXP: zie "EXP". Niet bewaren beneden **+4°C.** **BE:** Geneesmiddel op medisch voorschrift **BE: BE327591** **NL: RVG 23960-UR**	Lire la notice avant utilisation. Stérile et exempte d'endotoxines bactériennes. Vérifier l'intégrité de l'emballage. A utiliser seulement si la solution est limpide. A usage unique. Les quantités de solution non utilisées doivent être jetées. Ne pas utiliser avec un générateur d'hémodialyse. Ne pas injecter directement : mélanger les deux compartiments avant utilisation. Mélanger les additifs avant de connecter cette poche au circuit extracorporel. Tenir hors de la vue et de la portée des enfants. Pour connaître la durée de conservation du médicament reconstitué, consulter la notice d'utilisation. Lot : voir "LOT". EXP : voir "EXP". Ne pas conserver en dessous de : **+4°C.** **FR: Médicament autorisé n°: 3400938382938** Médicament soumis à prescription médicale. Liste I - Uniquement sur ordonnance. Respecter les doses prescrites. **BE:** Médicament soumis à prescription médicale **BE: BE327591** **LU: 2009010011**

A 250 ml
B 4750 ml

HEMOSOL B0

Hämodialyse-/Hämofiltrationslösung | Oplossing voor hemodialyse/hemofiltratie | Solution pour hémodialyse/hémofiltration
Kaliumfrei | Kaliumvrij | Sans potassium
Zur intravenösen Anwendung und/oder kontinuierlichen Hämodialyse |
Voor intraveneus gebruik en/of continue hemodialyse | Voie intraveineuse et/ou hémodialyse/hémofiltration continue

1000 ml Lösung enthalten | Elke 1000 ml bevat | Formule pour 1000 ml		
Vor dem Mischen | Voor reconstitutie | Avant reconstitution	**A**	**B**
Calciumchlorid | Calciumchloride | Chlorure de calcium, 2 H_2O	5,145 g	
Magnesiumchlorid | Magnesiumchloride | Chlorure de magnésium, 6 H_2O	2,033 g	
Milchsäure | Melkzuur | Acide lactique	5,400 g	
Natriumchlorid | Natriumchloride | Chlorure de sodium		6,450 g
Natriumhydrogencarbonat | Natriumbicarbonaat | Bicarbonate de sodium		3,090 g
Sonstige Bestandteile | Lijst van hulpstoffen | Liste des excipients : Wasser für Injektionszwecke, Kohlendioxid | Water voor injecties, koolstofdioxide | Eau pour préparations injectables, dioxyde de carbone		
Nach dem Mischen | Na reconstitutie | Après reconstitution, A + B		

	Ca^{2+}	Mg^{2+}	Na^+	Cl^-	$C_3H_5O_3^-$	HCO_3^-
mmol/l	1,75	0,5	140	109,5	3	32
mEq/l	3,50	1,0	140	109,5	3	32

Theoretische Osmolarität | Theoretische osmolariteit | Osmolarité théorique : 287 mOsm/l

5000 ml
Product No.: 112084

Pharmazeutischer Unternehmer | Registratiehouder | Titulaire de l'autorisation de mise sur le marché :
Baxter Holding B.V., Kobaltweg 49, 3542CE Utrecht, Niederlande | Nederland | Pays-Bas
FR: Exploitant : BAXTER SAS, Immeuble Berlioz, 4 bis rue de la Redoute 78260 Guyancourt, FRANCE

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07-25-00-1628

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	UK Hemosol B0 Product code 114229	Hemosol B0 FR/NL/DE language Product code 112084
Bag peel seal	Open seal ↓ Otworzyć zgrzew ↓ Odprite tesnilo ↓ D05700042 Rev. 2015-02	Die Trenn-Naht öffnen ↓ Ouvrir la soudure pelable ↓ Open de lasnaad ↓ D05700031 Ver. 1.0
Code Specific Carton Label