

Date: May 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Finomel Emulsion for Infusion (1435ml - 1101320) Interim Supply of Belgian Stock to Mitigate Supply Disruption

(42% glucose solution, a 10% amino acid solution with electrolytes, and a 20% lipid emulsion)

Dear Healthcare Professional,

Summary: Baxter Healthcare Ltd is currently experiencing supply disruption with Finomel Emulsion for Infusion, in the UK.

To ensure continuity in supply during the current Covid-19 situation, Baxter has obtained approval from the MHRA to supply Belgian product NQM19001; 4 x 1435ml, which is expected to be on the UK market from June 2020 to December 2020.

Please note the following:

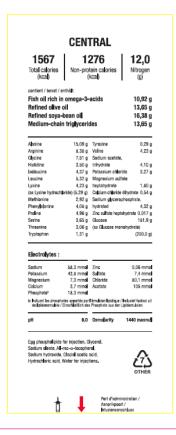
- This product is considered licensed in the UK (PL00116/0661).
- The product from Belgium has the same formulation as the UK product
- The product from Belgium is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Belgian and UK product information. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved <u>SPC</u> and PIL supplied with the United Kingdom packs. Discard the Belgium leaflet in the pack.
- For additional copies of the leaflet, please contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

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

Images of imported product if labelling differs from standard UK product:

(Note that the labelling is the same; the only differences are the name of the product and the language)









Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, 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 effect 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, treatment dates, and product brand name.

Company contact point

If you have any clinical questions about the information contained in this letter, or the use of Finomel Emulsion for Infusion, please contact Baxter Medical Information on 01635 206345 or email

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Kind Regards

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