

Fresenius Kabi Limited Cestrian Court Eastgate Way Manor Park Runcorn WA7 1NT United Kingdom www.fresenius-kabi.co.uk

18 August 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Fresenius Propoven 2% Emulsion for Injection or Infusion (propofol): Interim Supply of European Stock to Mitigate Supply Disruption

Dear Healthcare Professional

In order to prevent a supply disruption with Fresenius Propoven 2% Emulsion for Injection or Infusion (propofol) in the UK, Fresenius Kabi Limited is providing European stock.

To ensure continuity in supply during the current Covid-19 situation, Fresenius Kabi Limited has obtained approval from the MHRA to supply European product (batch number 16PD7581; 56,390 100 ml vials), which is expected to be on the UK market from September to December 2020.

Please note the following:

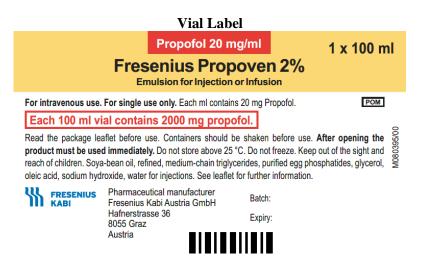
- This product is considered licensed in the UK.
- The product has the same formulation as the UK product. The only difference is the vial size of 100ml instead of the currently supplied 50ml vials.
- The product is manufactured according to the same manufacturing process and quality controls as the UK product.
- Please note that this pack is provided in English language with an English language leaflet. The text is the same as the UK product except that it does not contain the UK licence holder's address (which is given at the top of this letter) or Product Licence number (PL 08828/0168), only the manufacturing site details.
- 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.





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Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <u>https://www.gov.uk/yellowcard</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 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 questions about this letter or wish more information about **Fresenius Propoven 2% Emulsion for Injection or Infusion,** please contact Fresenius Kabi Limited at <u>medical.information-UK@fresenius-kabi.com</u>.

Yours faithfully,

Mr Fernando Correia Senior Regulatory Affairs Officer Fresenius Kabi Limited