

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.

**Outer Carton Label**


**Propofol 20 mg/ml 10 x 100 ml**


**Fresenius Propoven 2%**  
Emulsion for Injection or Infusion

For intravenous use. Each ml contains 20 mg propofol.  
**Each 100 ml vial contains 2000 mg propofol.**

For single injection or infusion in an individual patient.  
Containers should be shaken before use. Use only if the emulsion is homogeneous and the container undamaged. Any unused emulsion must be discarded. Not a multiple use container. Prior to use, the rubber membrane should be cleaned using an alcohol spray or a swab dipped in alcohol. Use only under aseptic conditions. Read the package leaflet before use. **After opening the product must be used immediately.** Do not store above 25 °C. Do not freeze. Keep out of the sight and reach of children. Soya-bean oil, refined, medium-chain triglycerides, purified egg phosphatides, glycerol, oleic acid, sodium hydroxide, water for injections. See leaflet for further information.


PC: 04052682040665


Batch: 


Expiry: 

**FRESENIUS  
KABI**  
Pharmaceutical manufacturer  
Fresenius Kabi Austria GmbH  
Hafnerstrasse 36  
8055 Graz  
Austria

PC: 04052682040665

Batch: 

Expiry: 



**Vial Label**

**Propofol 20 mg/ml** **1 x 100 ml**

**Fresenius Propoven 2%**  
Emulsion for Injection or Infusion

For intravenous use. For single use only. Each ml contains 20 mg Propofol.

**POM**

**Each 100 ml vial contains 2000 mg propofol.**

Read the package leaflet before use. Containers should be shaken before use. **After opening the product must be used immediately.** Do not store above 25 °C. Do not freeze. Keep out of the sight and reach of children. Soya-bean oil, refined, medium-chain triglycerides, purified egg phosphatides, glycerol, oleic acid, sodium hydroxide, water for injections. See leaflet for further information.

M080395/00



Pharmaceutical manufacturer  
Fresenius Kabi Austria GmbH  
Hafnerstrasse 36  
8055 Graz  
Austria

Batch:

Expiry:



**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 questions about this letter or wish more information about **Fresenius Propoven 2% Emulsion for Injection or Infusion**, please contact Fresenius Kabi Limited at [medical.information-UK@fresenius-kabi.com](mailto:medical.information-UK@fresenius-kabi.com).

Yours faithfully,



Mr Fernando Correia  
Senior Regulatory Affairs Officer  
Fresenius Kabi Limited