

Direct Healthcare Professional Communication**IMPORTANT DRUG SAFETY INFORMATION:****Suxamethonium – Temporary foreign label product
Label and patient information leaflet (PIL) is in Portuguese**

April 2020

Dear Healthcare Professional,

B Braun Medical Ltd in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA), NHSE and Commercial Medicines Unit (CMU) would like to inform you of the following:

For a temporary period during the COVID-19 Pandemic, B Braun will be supplying your NHS Trust with Suxamethonium which is manufactured by B Braun and imported from Portugal with a Portuguese label and PIL (Patient Information Leaflet). The reason for this is to help with continuity of supply of a critical medicine to the NHS. This is an unlicensed medicine in the UK as it is foreign label product however it is licensed in the EU.

A copy of the Summary of Product Characteristics in English is provided with this letter.

Summary:

For a temporary period of time during the COVID-19 Pandemic the label and PIL for Suxamethonium will look different to usual stocks.

- The labels are written in Portuguese
- The PILs are written in Portuguese
- The product is called Mioflex Braun 100 mg/2 ml Solução injetável
- B Braun can confirm that the product is the same as Suxamethonium 100mg/2ml
- Please verify the dose carefully before dispensing and administering
- Please find enclosed a copy of the English text translation for the SmPC (Summary of Product Characteristics)

Please find below an image of the temporary label for Suxamethonium presentations (Mioflex B Braun) supplied by B Braun:



Please continue to be vigilant and to report suspected adverse reactions with Suxamethonium to the MHRA via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. In addition, adverse drug reactions should be reported to the Medical Information Department at B Braun Medical Ltd UK via telephone on 0800 298 0299 or via email at medinfo.bbmun@bbraun.com.

If you have further questions or require additional information or relevant information on product administration, please contact the B. Braun Medical Information Team on 0800 298 0299.

Yours sincerely

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