



Pfizer Limited

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DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

**Trumenba 60 µg/dose suspension for injection
(meningococcal group B vaccine (recombinant, adsorbed))
Provision of packs in foreign language**

Dear Healthcare Professional,

Summary: Pfizer is temporarily providing foreign language packs for Trumenba 60 µg/dose suspension for injection (meningococcal group B vaccine (recombinant, adsorbed)) in the UK

As part of Pfizer's commitment to ensure market supply of Trumenba 60 µg/dose suspension for injection, and due to the significant increase in demand directly driven by the recent meningococcal serogroup B outbreak, the MHRA has agreed to an exemption according to Regulation 266 of HMRs 2012 No 1916, from the obligation that certain particulars should appear on the outer and immediate packaging of Trumenba 60 µg/dose suspension for injection and that the information must be given in English. This is to allow the temporary distribution of packs in foreign language, approved for use in EU countries.

Please note the following:

- The medicinal product is the same as normally supplied in the UK, with the only difference being the language of the packaging and the Product Information enclosed in each pack.
- To offset the language difference, please ensure that a copy of the printed UK Patient Information Leaflet, sent alongside this order, is delivered with each vaccination.
- Digital versions of the UK SmPC and PIL can be accessed from Trumenba (meningococcal group B vaccine (recombinant, adsorbed)) page on <https://www.medicines.org.uk/emc/>.

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

Call for reporting

Please continue to report suspected adverse reactions (ADRs) to the MHRA through the Yellow Card Scheme at www.mhra.gov.uk/yellowcard, search MHRA Yellow Card in the Google Play or Apple App Store, or some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals. Adverse events can also be reported to Pfizer Pharmacovigilance, Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS e-mail: GBR.AEReporting@pfizer.com Fax: 0845 300 8032 Web: www.pfizer.co.uk

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates, alongside the batch number and name of the medicine.

Company contact point

Should you require any additional information, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or telephone: 01304 61 61 61.

Sincerely,

Monica Nijher, MD
Vice President UK Country Medical Director