Date: 1st October 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Semglee®▼ 100 units/ ml x 3ml prefilled pens (Insulin glargine):

Interim Supply of Portuguese Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Mylan is currently experiencing supply disruption with Semglee® 100 units/ ml x 3ml prefilled pens (Insulin glargine) in the UK.

Due to unavoidable circumstances related to the current Covid-19 situation, we have experienced an increased demand of Semglee® and anticipating a temporary supply constraint. To ensure continuity in supply during this period of disruption, Mylan has obtained approval from the MHRA to supply Portuguese product:

Batch Number	Quantity (no. of packs)	Expiry	Origin
BF 18007531	6,533	31/08/2021	Portugal

Please note the following:

- This product is considered licensed in the UK.
- The product from Portugal has the same formulation as the UK product
- The product from Portugal is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are differences between the Portuguese and UK product information. The language is different.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved SPC supplied electronically and PIL enclosed in a plastic bag attached to the carton of Portuguese packs with patient letter. Discard the Portuguese leaflet in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/9815 or contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation in accordance with regulation 266(4)(a) and 266(4)(b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Semglee® and that certain aspects of the labelling do not appear in English.

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

Generics [UK] Ltd t/a Mylan, Building 4, Trident Place, Mosquito Way, Hatfield, Herts, AL10 9UL

Tel Nº: +44 (0)1707 853000 Fax Nº: +44 (0)1707 261803

Registered Office: Station Close, Potters Bar, Herts, EN6 1TL Registered in England Nº 1558756

Reporting of Adverse Reactions

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. It allows continued monitoring of the benefit/risk balance of the medicinal product. In order to support effective tracking and traceability of biologics including biosimilars, it is recommended that the brand name and batch number are recorded and used when reporting adverse reactions. Please continue to report suspected adverse reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme.

It is easiest and quickest to report ADRs online via the Yellow Card website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary), by emailing yellowcard@mhra.gov.uk, at the back of the British National Formulary (BNF), by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789, or by downloading and printing a form from the Yellow Card section of the MHRA website.

You can also report adverse reactions direct to the marketing authorisation holder at ukpharmacovigilance@mylan.com.

Company contact point

If you have any questions about this letter or wish more information about Semglee®, please contact Julian De Gabriele, Mylan UK Healthcare Limited info.uk@mylan.co.uk

Sincerely,

Julian De Gabriele

Head of Medical, UK

Generics [UK] Ltd t/a Mylan, Building 4, Trident Place, Mosquito Way, Hatfield, Herts, AL10 9UL

Tel Nº: +44 (0)1707 853000 Fax Nº: +44 (0)1707 261803

Registered Office: Station Close, Potters Bar, Herts, EN6 1TL Registered in England Nº 1558756