

PRODUCT RECALL

Emerade 150 micrograms solution for injection in pre-filled pen PA1696/009/001

Emerade 300 micrograms solution for injection in pre-filled pen PA1696/009/002

Emerade 500 micrograms solution for injection in pre-filled pen PA1696/009/003

All in-date batches

30th September 2019

Dear Wholesaler,

We wish to advise you that all in-date batches of the above-listed Emerade products are being recalled with immediate effect.

This recall is going to **patient level**.

This action has been agreed with the Health Products Regulatory Authority (HPRA).

The reason for the recall is that a number of reports of failure to activate have recently been received for Emerade pens. The cause of these activation failures and the defect rate remain unknown. This is a separate issue to the potential needle blockage issue for Emerade pens which was previously communicated to the Irish market. It is possible therefore for both defects to be present in a pen with the potential for failure of administration of this potentially life-saving medication.

Please immediately quarantine any units of these products which you have in your possession.

Please return all units to your wholesaler by 25th October 2019 to receive credit.

If you have supplied any in-date units of these products to any other wholesaler, please send those wholesalers a copy of this recall letter, requesting that they quarantine and return any unsold in-date quantities of the product to you.

We apologise for any inconvenience this action may cause.

Unaffected replacement stock is not currently available to order.

Contacts for further information:

For any recall or customer service enquiries please contact Bausch Health Customer Services,
Telephone number: +44 208781 2991, Email: Pharma_CS@bausch.com

A handwritten signature in blue ink, appearing to read 'Fintan Browne', with a stylized flourish at the end.

Fintan Browne
Bausch Health Ireland Limited