BAUSCH Health

3013 Lake Drive,
Citywest Business Campus
Dublin 24,
Ireland

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 Pharmacist,

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 on other markets. 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 you via the Caution in Use communications of July 2018 and July 2019. It is possible, however, 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. For hospital pharmacies, this includes wards, clinics, units at paramedic level and any other relevant locations within your facility.

Quarantined units will be uplifted by your wholesaler. Please complete the attached fax-back form, indicating to your wholesaler the number of units which require uplift. The last date by which stock will be received back for credit is two weeks from receipt of this letter.

We are requesting that all in-date packs of Emerade 150 mcg, Emerade 300 mcg and Emerade 500 mcg are recalled from patients.

- Please check your dispensing records to identify patients to whom Emerade 150 mcg, Emerade 300 mcg and / or Emerade 500 mcg has been dispensed. As the shelf life of the Emerade products is 18 months, the earliest relevant dispensing date is April 1st 2018.

- Please endeavour to contact those patients or their carers by telephone, to ascertain if they have any unused units of Emerade 150 mcg, Emerade 300 mcg and / or Emerade 500 mcg. If units are identified by the patient or carer, please request that they return the units to you at their earliest opportunity, for replacement with an alternative product.

- In line with the advice for patients to carry two adrenaline auto-injector pens, patients should be dispensed two pens of the same type.

- Please advise patients to familiarise themselves with the instructions for use of their new pen. Advise them to read the package insert, to visit the company's website where instructional videos and Apps are available and simulator devices can be accessed.

- Alternative adrenaline auto-injector products are available to order. Please ensure that the requisite number of pens of an alternative product(s) is ordered from your wholesaler, to replace all pens returned by your patients. This should be done as a priority so that unaffected units are available to provide to patients, should they return their Emerade pens to you.

- Please quarantine any packs that are returned to you by a patient or carer. Please contact your wholesaler to arrange for uplift, as detailed on the attached fax-back form.

If you have supplied in-date units of these products to a G.P., clinic, another pharmacy, paramedic or any other party, please contact them so that they can return the units to you for quarantine and uplift.

Unaffected replacement stock of Emerade is not available to order at this time.

For Hospital Pharmacists only:

We request that this communication is highlighted and made available to the relevant healthcare professionals within your hospital, for example; Immunologists, Dermatologists, , Emergency Medical Officers and Paediatricians.

We apologise for any inconvenience this action may cause.

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.

Reporting of suspected adverse reactions:

Any side effects should be reported. This includes any possible side effects not listed in the package leaflet. You can report side effects directly to the HPRA. The address is: HPRA Pharmacovigilance, Kevin O'Malley House, Earlsfort Terrace, Dublin 2. You may also report via telephone at +353 1 6764971, by Fax: +353 1 6762517, via the website: www.hpra.ie and by e-mail: medsafety@hpra.ie.

By reporting side effects, you can help provide more information on the safety of this medicine.

Adverse events can also be reported to Bausch Health directly on +44 208 781 5523 or by e-mail at Pharmacovigilance.UK@bausch.com.

Fintan Browne

Bausch Health Ireland Limited