BAUSCH + LOMB
A Company of Valeant Pharmaceuticals International, Inc.

Bausch + Lomb UK Ltd
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Address

Date 2nd July 2018

Dear Pharmacist,

Caution-In-Use Notification

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

Following discussions with the Health Products Regulatory Authority (HPRA), Bausch + Lomb, acting on behalf of the Marketing Authorisation Holder for Emerade, wishes to alert you of the following potential quality defect:

- There is a possibility that a small percentage (0.015%) of Emerade pens on the Irish market may not deliver a dose of adrenaline.
- This is due to the potential for a blocked syringe needle to be in place.
- A blocked needle has been identified by the manufacturer in one Emerade syringe during standard product stability testing.
- While no confirmed reports of a blocked needle have been received from the marketplace for Emerade to date, there is the potential for units on the market to have a blocked needle, and this could lead to an Emerade auto-injector not firing.
- **The risk presented by this defect can be reduced by the patient always carrying two pens as described in the approved patient information for Emerade.**

For All Pharmacists:

We request that the following instructions are followed and disseminated within your pharmacy, as appropriate:

1. Please endeavor to contact patients to whom you have dispensed any in-date batch of Emerade. (The shelf-life of Emerade is 18 months, so the earliest relevant dispensing date would be January 2017.)

2. If any patient that you contact is in possession of an in-date Emerade pen, please remind them of the importance of always carrying two Emerade pens, in accordance with the Package Leaflet.

3. When dispensing new Emerade pens, please ensure that all patients are advised to carry two pens at all times, in accordance with the Package Leaflet.

For Hospital Pharmacists only:

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

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 affects you can help provide more information on the safety of this medicine.

Adverse events can also be reported to Bausch + Lomb directly on +44 1748 828864 or by e-mail at **Pharmacovigilance.UK@bausch.com**

We apologise for any inconvenience this issue may cause. Should you have any queries, please email **Pharmacovigilance.UK@bausch.com** or contact Bausch + Lomb on +441748 828864.

Yours sincerely,

Jenni White

Jenni White
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