Medicines & Healthcare products Regulatory Agency

D R U G A L E R T

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use – Action within 72 hours
Notification to Patient Level

Date: 11 July 2019 EL (19)A/17 Our Ref: MDR 55-06/18

Dear Healthcare Professional,

Pharmaswiss Česka republika s.r.o. (an affiliate of Bausch & Lomb UK Limited)

Emerade 150 micrograms solution for injection in pre-filled syringe	**PL 33616/0013**
Emerade 300 micrograms solution for injection in pre-filled syringe	**PL 33616/0014**
Emerade 500 micrograms solution for injection in pre-filled syringe	**PL 33616/0015**

(Adrenaline)

Brief description of the problem

- Bausch & Lomb UK limited has informed us of a risk of Emerade product failing to deliver a dose of adrenaline from the syringe due to blockage of the needle.
- This issue was first detected in June 2018 during routine stability testing of the syringe component of Emerade, with potential to affect 1.5 in every ten thousand pens, and therefore considered a rare event. However, recent information indicates that the potential occurrence of needle blockage in batches on the market is higher than first estimated and we are therefore bringing it to the attention of patients.
- The potential for units on the market to have a blockage of the needle which could lead to Emerade failing to deliver a dose when activated is now estimated to be 0.23 %*, which would affect 2.3 in every thousand pens. However, if the patient follows the existing advice to carry

two in-date pens with them at all times, the risk of not being able to deliver a dose of adrenaline before the emergency services arrive is substantially reduced (from 0.23% to 0.000529%).

** This estimate is based on simulated laboratory conditions without the auto-injector component which may lower the potential rate of failure to deliver.*

- It should be emphasised that two pens are already recommended to be carried at all times in case the patient does not improve after the first injection which may occur for a number of reasons.
- This notification of potential for needle blockage applies to Emerade devices of all strengths. It does not apply to the other marketed brands of adrenaline auto-injectors.
- The MHRA is not recalling batches of Emerade.
- In the UK there are two alternative adrenaline auto-injector devices available. However, the different brands of adrenaline auto-injectors are not used in exactly the same way and therefore specific training and advice is required for each of the devices.
- Furthermore, there are insufficient supplies available of alternative brands to support the removal of one brand.
- The manufacturer conducted extensive investigations and has implemented corrective actions. Emerade manufactured with all the corrective processes is expected to be introduced into the market from mid-July 2019.

Action for healthcare professionals and patients

- **Healthcare Professionals should contact all patients, and their carers, who have been supplied with an Emerade device to inform them of the potential defect and reinforce the advice to always carry two in-date adrenaline autoinjectors with them at all times.**
- This advice is provided in the approved patient information leaflet for Emerade, which should be provided to the patient or caregiver at dispensing.
- Patients experiencing any problem with Emerade failing to activate should report this via the MHRA's Yellow Card system and keep the pen for further examination: https://yellowcard.mhra.gov.uk/

Additional advice to reiterate to patients is:

- Check expiry date and replace the pen before it expires
- Use the autoinjector at first signs of anaphylaxis
- Call 999, ask for an ambulance and say anaphylaxis (pronounced as *'anna -fill-axis')*
- Lie flat if possible with your legs up to keep your blood flowing
- Use second pen if still unwell after 5-15 minutes

See https://assets.publishing.service.gov.uk/media/5b644e25ed915d377695c83d/AAI-PDF-v4.pdf for a sheet to provide to patients and carers in this discussion

- The risk of device mishandling or device failure exists with all adrenaline auto-injectors and is something that patients and carers should be aware of.
- The chance of a successful outcome is increased if there is prompt administration of adrenaline at the first signs of anaphylaxis.
- Even with an apparently successful response to adrenaline autoinjector administration, patients may relapse some hours later which underlines the importance that the emergency services should always be called.

Contacts for Further Information:

For stock enquiries please contact Bausch & Lomb Customer Services**,** Tel: 0208 781 2991
Email: Pharma_CS@bausch.com

For medical information enquiries please contact Lizanne Kombrink (Pharmacovigilance and Medical Information Officer), Tel: 0208 781 5523, Email: Pharmacovigilance.UK@bausch.com

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional Teams are asked to forward this to relevant clinics, general practitioners and community pharmacists for information / action.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574

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