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4th October 2021

Emerade 300 microgram and 500 microgram adrenaline auto-injectors: re-supply to market – important safety information

Dear Healthcare Professional,

PharmaSwiss Česká republika s.r.o., an affiliate of Bausch & Lomb U.K. Limited ("Bausch + Lomb"), in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), is able to inform you that Emerade 300 microgram and 500 microgram adrenaline auto-injectors will be resupplied to the market in October 2021, following corrections made to the device.

Summary

- **Emerade adrenaline auto-injectors were recalled in 2020 due to an error in one component that caused some auto-injectors to fail to activate and deliver adrenaline.**
- **Following satisfactory implementation of corrective actions, the MHRA has agreed that the 300 microgram and 500 microgram strengths of Emerade adrenaline auto-injectors can be re-supplied to the market.**
- **Healthcare professionals should follow advice in the Summary of Product Characteristics on dosing recommendations.**
- **Emerade 150 microgram auto-injectors will not be returning to market at this time, further details of re-supply will be provided at a later date.**

Important Safety Information regarding all adrenaline auto-injectors:

- **Specific training and advice should be provided to patients and their caregivers on how to use their adrenaline auto-injector. This is specific to each brand and therefore patients must receive training specific to Emerade. Patients and caregivers are recommended to obtain trainer auto-injectors to assist familiarity in use.**
- **Remind patients to follow existing advice to carry two in-date adrenaline auto-injectors with them at all times and to replace them before they expire.**
- **Advise patients they should:**
    1. **Use the adrenaline auto-injector at the first signs of anaphylaxis.**
    2. **Call 999, ask for an ambulance, and say anaphylaxis .**
    3. **Lie flat, with their legs up to keep blood flowing.**
    4. **Use a second auto-injector if still unwell after 5 to 15 minutes.**
- **Any potential issues or suspected device failures encountered when operating an adrenaline auto-injector should be reported to the MHRA's Yellow Card scheme promptly.**

Call for reporting

Please report suspected adverse drug reactions (ADRs) or suspected defective medicines to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website: https://yellowcard.mhra.gov.uk/
- the free Yellow Card app available from the Apple App Store or Google Play Store.
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Contact details for the MHRA's Defective Medicines Reporting Centre, including out of hours, can be found on the MHRA's website: https://www.gov.uk/guidance/contact-mhra#defective-medicines-reporting-centre

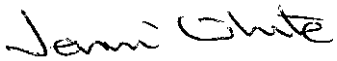
Contacts for Further Information:

For stock enquiries please contact Bausch + Lomb Customer Services**,** Tel: 020 8781 2991,
Email: Pharma_CS@bausch.com

For medical information enquiries please contact the Pharmacovigilance and Medical Information Officer, Tel: 0800 041 8721, Email: ukmedinfobausch@biomapas.com

Bausch + Lomb is committed to helping ensure patients have access to the medicines they need, including life-saving medicines such as Emerade.

Yours faithfully,



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