National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

Recall of Emerade 500 micrograms and Emerade 300 micrograms auto-injectors, due to the potential for device failure

Date of Issue:	09-May-23	**Reference No:**	NatPSA/2023/004/MHRA

This alert is for action by: primary and secondary care, specifically those involved in General Practice (GP) and pharmacy services, including dispensing general practices.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) supported by Chief Pharmacists, or equivalent roles, as well as leaders in general practice and community pharmacy.

DMRC Medicines Defect Classification	NatPSA equivalent to Class 1 Recall Notification

Explanation of identified safety issue:

Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited is recalling all unexpired batches of Emerade 500 micrograms and Emerade 300 micrograms adrenaline auto-injectors (also referred to as pens) from patients. This is due to an issue identified during an ISO 11608 Design Assessment study where some auto-injectors failed to deliver the product or activated prematurely.

Specifically, the 1-metre free-fall (vertical orientation) pre-conditioning resulted in damage to internal components of the auto-injector, leading either to failure to deliver the product or premature activation. This damage was not visibly apparent following the pre-conditioning but was evident only on subsequent functional testing. It is unclear what impact this has on auto-injectors in clinical use, however as a precautionary measure and owing to the inability to identify this issue before the auto-injectors are used, the auto-injectors are being recalled.

The MHRA, in conjunction with the Department of Health & Social Care (DHSC) has established that there are sufficient supplies of alternative auto-injectors to allow for a recall at patient level. Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited has confirmed that future production of Emerade 500 micrograms and Emerade 300 micrograms auto-injectors is on hold. Therefore, no further supplies will be available, and patients will need to be switched to an appropriate alternative.

Healthcare professionals should inform patients, or carers of patients, who carry Emerade 300 or 500 microgram auto-injector pens to obtain a prescription for and be supplied with an alternative brand. They should then be informed to return their Emerade 300 or 500 microgram pens to their local pharmacy.

Actions required

Actions required to complete by 12 May 2023:

The action to recall should be coordinated by the Chief Pharmacist/Superintendent Pharmacist/Responsible Pharmacist, Dispensing GPs and GP practices in the first instance. The below actions should be initiated by General Practitioners (GPs) and Pharmacy Teams immediately.

1. Stop supplying the impacted products immediately. Quarantine all remaining stock and return it to your supplier/MAH using your supplier's approved process.

2. Identify patients who have been supplied with Emerade 500 micrograms and Emerade 300 micrograms auto-injectors and ensure that they are reviewed by their prescriber to determine whether their adrenaline auto-injector prescription is still appropriate and in line with existing guidance.

3. Immediately inform patients and carers to request a new prescription to replace each Emerade 500 micrograms and Emerade 300 micrograms auto-injector with an equivalent strength adrenaline pen in an alternative brand. Healthcare professionals should be aware that the licensed dosing recommendations for each brand of pen are not identical. Dosing recommendations are available in the Summary of Product Characteristics (SmPC) and should be followed.

4. Inform patients to return Emerade 500 micrograms and Emerade 300 micrograms auto-injectors to any pharmacy after they have obtained a total of two equivalent strength adrenaline pens in an alternative brand.

General Practitioners (GPs) and Pharmacy Teams should send the linked letter "Advice for patients who have been prescribed Emerade auto-injectors", to all patients and carers who have been prescribed Emerade auto-injectors. See reference information on page 2 for link.

For further detail, resources and supporting materials see: www.gov.uk/drug-device-alerts

For any enquiries about this alert contact: DMRC@mhra.gov.uk

Additional information:

Product Information: Pharmaswiss Česka republika s.r.o. and distributor Bausch & Lomb UK Limited
Defective Medicines Report Centre Reference: MDR 020-05/23

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

Further advice for healthcare professionals: inform patients: that they should carry two in-date adrenaline auto-injectors with them at all times in case they need to administer a second dose of adrenaline before the arrival of the emergency services; that they need to receive training so they are confident in being able to use any new devices (see further information in the attached document); of the signs of anaphylaxis and the actions they should take immediately (see Management of Anaphylaxis in the recall notification for further advice).

Healthcare professionals should be aware that this recall also applies to Emerade 500 micrograms and Emerade 300 micrograms auto-injectors currently held by schools and in emergency anaphylaxis kits held by healthcare professionals, such as dental surgery kits etc. See further information in the links below.

Different brands of adrenaline pens work differently. Patients and carers should be told of these important differences. Healthcare professionals – doctors, nurses and pharmacists – should, where possible, ensure that they provide training to patients and carers in correct use of their new pen. Instructions for use can be found in the SmPC (prescriber's information) and in the Patient Information Leaflets (PILs) supplied with the different pens and on the respective manufacturers' websites, where training videos are available. Training pens that do not contain adrenaline can also be obtained free of charge from manufacturers. Healthcare professionals and patients are strongly recommended to obtain these to assist with training. The trainer pens can be used repeatedly, allowing patients to practice regularly with them so they are prepared for use in an emergency. The following links provide training materials for the different devices:

- EpiPen® 0.15mg: https://www.medicines.org.uk/emc/product/4290/rmms
- EpiPen® 0.3mg: https://www.medicines.org.uk/emc/product/4289/rmms
- Jext® 150 Training Video: https://www.medicines.org.uk/emc/product/5747/rmms
- Jext® 300 Training Video: https://www.medicines.org.uk/emc/product/5748/rmms

What to do if you suspect anaphylaxis

- administer an adrenaline auto-injector device without delay, even if there is doubt whether it is anaphylaxis
- call an ambulance (999) immediately after giving the injection and say this is an emergency case of anaphylaxis
- if you are not already lying down, then do so
- administer a second auto-injector 5 minutes after the initial dose, if no improvement is seen or if the patient deteriorates after an initial improvement
- patients should be advised to use a second adrenaline auto-injector immediately if the first adrenaline autoinjector pen fails to activate despite pressing firmly against the thigh (pictorial guidance on whether an Emerade pen has activated or not is given below)
- make further attempts to activate a failed adrenaline autoinjector pen while waiting for the ambulance if the patient is not improving, even if one pen has worked, as this may suggest a need for a second or more doses. The purpose of adrenaline pens is to start treatment for anaphylaxis that is continued by the emergency services.

For further information please refer to the MHRA's Adrenaline Auto-Injectors (AAIs) safety campaign - GOV.UK (www.gov.uk) We encourage patients and carers to read this fact sheet with advice on the use of adrenaline auto-injectors. 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 adrenaline is administered promptly at the first signs of anaphylaxis. Even with an apparently successful response to adrenaline auto-injector administration, patients may relapse some hours later, which underlines the importance of the emergency services being called.
Reference Information:

1. Class 1 Medicines Recall Notification including patient specific information – Click Here
2. Letter - Advice for patients who have been prescribed Emerade auto-injectors – Click Here (see download document section)

Defective Medicines Report Centre/ Medicines and Healthcare products Regulatory Agency
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Please check website www.gov.uk/drug-device-alerts for when actions should be ceased or advice to check for date restrictions are lifted.