NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

18th May 2020

Dear Prescribing Leads, Practice Managers and Pharmacists

URGENT ACTION REQUIRED FOR PATIENTS PRESCRIBED EMERADE 500 MICROGRAM AUTO-INJECTORS

Pharmaswiss Česka republika s.r.o. (an affiliate of Bausch & Lomb UK Limited) is recalling all unexpired batches of Emerade 500 microgram auto-injectors (also referred to as pens) from patients due to an error in one component of the auto-injector believed to cause some pens to fail to activate and deliver adrenaline.

The recall of Emerade 500 micrograms auto-injectors from patients follows a previous recall of Emerade 150 microgram auto-injectors and Emerade 300 microgram auto-injectors from patients.

More information on the previous alerts can be found on the following links:

Class 2 Medicines Recall: Emerade 150 micrograms solution for injection in pre-filled syringe, PL 33616/0013 (EL(20)A/14)

Class 2 Medicines Recall: Emerade 300 micrograms solution for injection in pre-filled syringe, PL 33616/0014 (EL(20)A/20)

Actions for Emerade 500 microgram auto-injectors

General Practitioners (GPs) should identify ALL patients prescribed Emerade 500 microgram auto-injectors within the last 2 years and send the attached Patient Letter – Advice for patients with an Emerade 500 microgram auto-injector to all patients and carers, as appropriate, who have been prescribed Emerade 500 micrograms auto-injectors.

- Identify patients who have been supplied with Emerade 500 micrograms autoinjectors and ensure they are reviewed to determine whether their adrenaline autoinjector prescription is still appropriate and in line with existing guidance.

- Immediately inform patients and carers to request a new prescription to replace each Emerade 500 microgram auto-injector with **one new 300 microgram adrenaline pen in an alternative brand**. Healthcare professionals should be aware that the licensed

dosing recommendations for each brand of pen are not identical. They are available in the Summary of Product Characteristics (SmPC) and should be followed.

- Inform patients to return Emerade 500 microgram auto-injectors to the pharmacy, only when they have **two alternative adrenaline 300 microgram auto-injectors in their possession.** ○ Although pens should be returned to a pharmacy once a replacement is obtained, this should not require someone who is self-isolating to leave their home (see COVID-19 advice below). ○ Pharmacists and pharmacies who receive Emerade 500 microgram autoinjectors from patients should quarantine the pens and return to them to their supplier using the supplier's approved process.
- Inform patients that they should always carry 2 in-date 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.

- Inform patients that they need to receive training, so they are confident in being able to use any new devices (see further information on this in relation to COVID-19 below).

- Ensure patients are aware of the signs of anaphylaxis and the actions they should immediately take.

- Ensure that patients and their carers understand that this recall also applies to Emerade 500 microgram auto-injectors that are currently held by schools.

- Prescribers should issue no more than two adrenaline auto-injectors per patient (of any brand or strength) unless: ○ Schools require separate pens to be kept on the school premises (e.g. in a medical room) in which case prescribers may need to consider issuing more than two but no more than four pens per child (of any brand or strength).
    - ○ For the rare scenario where patients might need more than two adrenaline pens prescribed (for example, a prior severe reaction resistant to treatment with adrenaline), where the prescriber may issue additional pens.

Information in relation to Coronavirus (COVID-19)

- When a prescription is needed for replacement pens, where possible, telephone appointments should be considered, based on the current UK Government guidelines for social distancing in relation to Coronavirus (COVID-19). Patients should be informed to follow the advice of their local GP practice/hospital and only attend where they are instructed to do so. See further information on COVID-19.
- Healthcare professionals involved in the dispensing process may wish to consider how to ensure that vulnerable patients and those practicing self-isolation, social distancing and shielding can still obtain their replacement auto-injectors, considering the use of delivery services where appropriate. Although pens should be returned to a pharmacy once a replacement is obtained, this should not require someone who is self-isolating or shielding to leave their home.
- At the present time, patients and carers may be unable to visit a healthcare professional to receive training in use of the new device. They must take particular care therefore to ensure that they read the instructions on how to use the pen in the leaflet contained in the box. Patients and carers should also consult training information for their new pen on the manufacturer's website This includes training

videos. All the manufacturers also provide trainer pens on request (mock pens that do not contain a needle or adrenaline) for patients and carers to practice with. Patients are strongly urged to obtain these.

Patients and carers should be told of the important differences between brands of adrenaline pen in how they are used.

- Healthcare professionals – doctors, nurses and pharmacists – should, where possible, ensure they provide training to patients and carers in correct use of the new pen. Instructions for use can be found in the SmPC (prescriber's information) and in the Patient Information Leaflets (PILs) that are 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 the 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:

- EpiPen® devices
- EpiPen® 0.15mg
- EpiPen® 0.3mg

Jext

- Jext® devices
- Jext® 150 Training Video
- Jext® 300 Training Video

To read the recall in full link below (MHRA Class 2 Medicines Recall: Emerade 500 micrograms solution for injection in pre-filled syringe, PL 33616/0015 (EL(20)A/23)).

https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-emerade-500-microgramssolution-for-injection-in-pre-filled-syringe-pl-33616-0015-el-20-a-23

If you have any queries about this recall please do not hesitate to contact our Medicines Optimisation Team via CAPCCG.prescribingpartnership@nhs.net for further support.

Kind regards

Medicines Optimisation Team