Department of Health

Supply Disruption Alert

SDA/2019/004 Issued: 01 August 2019 at 10:30 Valid until: 30th September 2019

Emerade 500 microgram and 300 microgram adrenaline auto-injector devices

Summary

Emerade 500 microgram and 300 microgram devices, manufactured by Bausch & Lomb UK, will be experiencing a short-term disruption in supply:

- Emerade 500 microgram: is out of stock until the 28th of August.
- Emerade 300 microgram: limited supplies remain available but will be out of stock from early-mid August with further supplies expected by the end of September.

The following management plan has been developed in collaboration with NHS England, the British Society for Allergy & Clinical Immunology (BSACI), the Medicines and Healthcare Products Regulatory Agency (MHRA) and National patient groups.

Action

All health care professionals in primary, secondary or specialist healthcare services who prescribe, dispense or administer adrenaline auto-injectors (AAIs), or who advise patients and their carers, should ensure that:

1. **All patients** prescribed Emerade 500 microgram and 300 microgram AAIs are identified and in cases where they require replacements during the shortage period the following should be actioned:

   a) Patients are reviewed to ensure their AAI prescription is still appropriate in line with existing guidance (see page 3 for further detail).
   b) Patients are made aware that an AAI device can be used until the end of the month listed as expiry. Therefore, the product expires on the last day of month indicated e.g. a device labelled ‘August 2019’ does not expire until the 31st August 2019.
   c) If replacement Emerade 500 microgram devices are required these should be replaced with a 300 microgram AAI device of an alternative brand and the patient should ensure they carry a minimum of 2 devices at all times. Those initially prescribed Emerade 300 microgram should have this replaced with an alternative brand in the same strength, when a new device is required. **Please note**, different brands of AAIs are not used in exactly the same way and therefore specific training and advice is required for each of the devices (further advice is provided on page 3).
   d) Where there is no patient / clinician preference EpiPen should be considered as the first line alternative because although supplies of both the AAI alternatives (Jext and EpiPen) are currently available, supplies of Jext are unlikely to be sufficient to support a significant switch to this product.
   e) Patients or carers are reminded to administer an AAI as soon as they experience symptoms of a severe allergic reaction and then call an ambulance stating they are having an “anaphylactic reaction”. Patients should administer a second auto-injector 5 mins after the initial dose, if no improvement is seen.
   f) On the rare occasion, and by exception, at the clinical judgement of the prescribing clinician, that consideration is given to prescribing of a vial of adrenaline to be drawn up by the patient for self-

administration via the intramuscular route. It should be recognised that although this would allow administration of a dose larger than 300 mcg per injection, this will require specific training.

g) AAIs should only be prescribed and dispensed to those who truly need them, as any additional issuing to patients with sufficient supplies who are worried about the shortages could exacerbate the overall supply situation (see page 3-4 for further guidance).
h) Due to the shortage, we ask that, when renewing the adrenaline in your anaphylaxis kits, all staff are alerted to please stock ampoules (ensuring you also include dosing charts, needles and syringes) and not AAIs.

2. Prescribers should work in close collaboration with their local pharmacies to understand which AAIs are available. Prescribers and pharmacists should work together to ensure patients who are switched to an alternative device are trained appropriately and understand how to use the new AAI

Action, to be taken by

- General Practices
- Community Pharmacies
- Acute Trusts
- Community Trusts
- Mental Health Trusts
- Ambulance Trusts

Deadlines for actions

Actions initiated: 1 August 2019
Actions completed: 30 September 2019

Product details

Emerade 500 micrograms (adrenaline tartrate) solution for injection in pre-filled pen.
Emerade 300 micrograms (adrenaline tartrate) solution for injection in pre-filled pen.

Problem / background

There is a short-term supply issue affecting Emerade 500 microgram and 300 microgram AAIs. Bausch & Lomb are the sole UK supplier of Emerade devices in the UK. This is caused by manufacturing issues experienced by their Swedish manufacturing partner, relating to its production line, which has led to a temporary decrease in output.

New supplies of Emerade 500 microgram are expected by the end of August 2019 and we are working with Bausch & Lomb UK to try and improve this date.

Limited stock of Emerade 300 microgram is available. Currently, new supplies are expected by the end of September 2019.

The MHRA issued a Caution in Use drug alert on 11 July 2019 relating to a defect that has the potential to have affected Emerade pens currently on the market and may result in failure to deliver a dose of adrenaline due to needle blockage.. It is estimated that 2.3 in every 1,000 pens in circulation could be affected. 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%).

New stocks of Emerade (all strengths) manufactured after the 30th of June 2019 will incorporate all corrective actions taken to rectify the potential for blocked needles.

In the UK there are two alternative AAI devices available, EpiPen, supplied by Mylan and Jext, supplied by ALK. However, neither of these companies supply a 500 microgram strength AAI. Both companies manufacture 300 microgram AAI pens. Both companies are aware of the supply disruptions affecting Emerade 500microgram and 300 microgram AAIs.

Both Jext and EpiPen AAIs are currently available, however, supplies of Jext are unlikely to be sufficient to support a significant switch to this product and therefore where there is no patient / clinician preference EpiPen should be considered as the first line alternative.

The advice from national experts is, in the absence of Emerade 500 microgram, affected patients should be prescribed 300 microgram AAIs and advised to keep at least two pens with them at all times.

To ensure that patients are able to maintain access to supplies of 300 microgram devices throughout this time we have asked Mylan to continue with their prescription validation process for pharmacies to order supplies of EpiPen 300 microgram. Further details are available at: www.epipen.co.uk.

Supplies of all 150 microgram devices (Emerade, Jext and EpiPen) are unaffected and remain available in volumes to support normal demand.

Existing Guidance

This section summarises the existing guidance that the actions are based on. It is intended as an easy reference summary of the existing guidance. All prescribers should review current guidance for when to prescribe adrenaline auto-injectors for adults and children that has been developed by the Standards of Care Committee (SOCC) of the British Society for Allergy and Clinical Immunology (BSACI), and also refer to the guidance in BNF and provided by manufacturers as appropriate.

https://www.bsaci.org/Guidelines/adrenaline-auto-injector

Regulatory advice for two adrenaline auto-injectors as the norm for most patients, once a need for an AAI prescription has been confirmed, should continue to be adhered to:

https://www.gov.uk/drug-safety-update/adrenaline-auto-injectors-updated-advice-after-european-review

https://assets.publishing.service.gov.uk/media/5b644e25ed915d377695c83d/AAI-PDF-v4.pdf

All patients should be reminded that at the onset of symptoms of anaphylaxis, they should:

- **Immediately use an adrenaline auto-injector device.**
- Immediately call an ambulance (999) or send someone to do this. Say this is an emergency case of anaphylaxis*

**Please note- ambulances carry adrenaline 1mg/1ml (1 in 1,000) ampoules, which are not affected by the shortage*

Consider if the initial prescription of AAIs is appropriate
Patients at risk of anaphylaxis that should be considered for long-term provision of an adrenaline auto-injector include those:

- who are allergic to high-risk allergens, for example nuts with other risk factors (such as asthma), even if the reaction was relatively mild
- who had a reaction in response to trace amounts of allergen/trigger
- who cannot easily avoid the allergen
- with continuing risk of anaphylaxis (e.g. food dependent, exercise-induced)
- with idiopathic anaphylaxis
- with significant co-factors (e.g. raised baseline serum tryptase)

The decision to prescribe requires a tailored, individual decision as part of a package of measures and is not a substitute for a referral to an allergy specialist. The decision to prescribe should be made by a clinician experienced in risk assessment in this context.

Adrenaline auto-injectors should be discontinued if the original prescription was inappropriate.

How many AAIs are required?

The majority of patients should have two AAI devices available at all times but there is existing flexibility within the prescriber information for the clinician, in exceptional cases, to prescribe one AAI, based on careful assessment of individual risk factors.

Which AAI devices can be used?
There are three adrenaline auto-injector devices available in the UK; EpiPen®, Jext® and Emerade® and all can be prescribed. The devices differ slightly in the administration technique and specific training is required for each device. The devices are not interchangeable without specific training on the device being issued to the patient. This is the responsibility of the prescriber and training may be accessed via pharmacists, practice nurses or allergy services.

The following links provide training materials for the different devices.

- EpiPen devices: http://www.epipen.co.uk/patients/epipenr-user-guide
- Jext devices: https://jext.co.uk/
- 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
- Emerade devices: https://www.emerade-bausch.co.uk/patient/how-to-use-emerade
- Emerade 150: https://www.medicines.org.uk/emc/product/5278/rmms
- Emerade 300: https://www.medicines.org.uk/emc/product/5280/rmms
- Emerade 500: https://www.medicines.org.uk/emc/product/5279/rmms

Adrenaline for anaphylaxis kits

- Some healthcare professionals may be holding Emerade, or other AAIs, in preference to adrenaline ampoules, to treat anaphylactic reactions; this should not be necessary.
- All healthcare professionals providing services where anaphylaxis treatment may be required, including but not exclusive to flu vaccination services, should have the competency to draw up and administer intramuscular adrenaline from ampoules with a normal syringe and needle.

Due to the shortage, we ask that, when renewing the adrenaline in your anaphylaxis kits, all staff are alerted to please stock ampoules (ensuring you also include dosing charts, needles and syringes) and not AAIs.

The Green Book and Resuscitation Council guidance provides additional advice to healthcare professionals on the use of adrenaline in response to anaphylaxis. Pharmacists providing vaccination services may also wish to refer to PSNC FAQs. Supplies of adrenaline ampoules are currently available and there is an expectation that healthcare professionals should use these in preference to the Emerade or similar devices.

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists; however, each organisation needs to ensure a senior clinician takes responsibility for coordinating all actions that need to be taken.

- General Practitioners
- Practice Nurses
- Chief Pharmacist
- Allergy specialists/allergy teams
- School Nursing/Medical Services
- Emergency Preparedness and Response Officer
- Medical Directors
- Pharmacists
- Paediatricians
- Paediatrics departments

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive Supply Disruption Alerts directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to the DH Supply Resilience Team, quoting reference number **SDA/2019/004**.

Email: supplyresiliencemd@dhsc.gov.uk

Addressees may take copies for distribution within their own organisations