Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

28 November 2019

Dear Emerade Adrenaline Autoinjector User,

The UK's regulator of medicines (Medicines & Healthcare products Regulatory Agency [MHRA]) has received reports of Emerade pens failing to activate. This means that in some cases, the needle is not released, and the injection of adrenaline is not delivered. This alert is an update to the previous drug alert issued on 03 October 2019. People in the UK who have been supplied with an Emerade are advised of the following:

Don't expose Emerade pens to heat or keep them somewhere hot

The company that makes Emerade (Bausch and Lomb UK Limited) has identified a fault in one part of Emerade autoinjectors that causes some pens not to activate and deliver adrenaline. This fault may be more likely to happen if the pen is exposed to temperatures higher than 25°C. Therefore, make sure you protect it from heat and do not leave your pen in a hot place (for example, in front of a heater, radiator, or fire). This instruction is not new, and you can find out more about how to store your pen safely in the leaflet that comes with it. Contact your doctor if you are planning to travel to somewhere hot since you may need a different pen for this trip.

Most pens will continue to work; carry two pens and use if you need to

In the UK, there are not enough adrenaline pens in alternative brands to replace all the Emerade pens held by patients. Most Emerade pens will continue to work. Therefore, the risk of not having a pen is much higher than the risk of having a pen that may not activate. If you have been given an Emerade pen, continue to use it as instructed (see next page). If your first Emerade pen does not activate despite firm pressure, immediately use your second pen. Always carry two adrenaline pens with you and use them if you need to.

When your Emerade pen expires, learn how to use your new type of adrenaline

When your Emerade pen has expired (the end of the month listed on the pen and case), you will be prescribed a different brand of adrenaline (EpiPen or Jext). There are some differences between brands. You and the people around you will need to be aware of these difference in how to use the pen(s) you have been supplied with. The manufacturers of the different devices have training information, including videos of how to use them correctly, on their websites. Trainer pens (mock pens that do not contain adrenaline) are also available to be ordered on the websites.

Further information can be found in the Patient Information Leaflets of the different pens.

- EpiPen - https://www.medicines.org.uk/emc/files/pil.4289.pdf
- Jext - https://www.medicines.org.uk/emc/files/pil.5748.pdf
- Emerade - https://www.medicines.org.uk/emc/files/pil.5278.pdf

What to do if you suspect anaphylaxis

Ensure you **carry two adrenaline pens with you at all times**. If you experience symptoms of anaphylaxis, administer an adrenaline pen without delay, even if you are not sure whether it is anaphylaxis. Early administration is vital. Immediately after administering an adrenaline pen, you or caregiver should dial 999, saying anaphylaxis (pronounced "anna-fill-axis") so that an ambulance is dispatched without delay.

A full investigation is still ongoing. The MHRA and Bausch and Lomb UK Limited will provide updated information to healthcare professionals and affected members of the public as soon as it becomes available. You can help us by continuing to report any issues directly via the Yellow Card reporting tool, https://www.gov.uk/yellowcard. Always include the brand and batch number included on your pen.

WHAT DOES MY EMERADE PEN LOOK LIKE BEFORE USE? Fig. 1

BEFORE USE

Instructions:

1. An unused Emerade pen, with front cap in place (Fig. 1).

2. For instruction on how to use your Emerade pen please consult the Patient Information Leaflet (PIL).

3. During this period, when activation failure is a possibility, you should press the Emerade pen very firmly against your thigh.

HAS MY EMERADE PEN ACTIVATED? Fig. 2

ACTIVATED
When Emerade Pen has been activated the needle cover will extend and lock.

Instructions:

1. After using an Emerade pen following the instructions found on product labelling, verify that the pen has activated.

2. An Emerade pen that has been activated, will have an extended needle cover (Fig. 2 – circled section of image)

3. Call 999 for an ambulance and state “Anaphylaxis” even if you start to feel better

4. Lie flat with your legs up to keep your blood flowing. However, if you are having difficulty breathing, you may need to sit up to make breathing easier

5. Proceed to administer your second pen if you are not improving after 5 to 15 mins in case you need a second dose of adrenaline

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WHAT DO I DO IF MY EMERADE PEN HAS NOT ACTIVATED? FIG. 3

NOT ACTIVATED
If the needle cover has not extended, the pen has not activated.

Instructions:

1. If the needle cover has not extended, the pen has not activated (Fig. 3 – circled section of image).

2. If the pen has not activated despite firm pressure, use the second pen immediately.

3. Call 999 for an ambulance and state “anaphylaxis” even if you start to feel better.

4. Perform additional attempts to activate, if
- Both pens have failed and no dose has been given;
- One pen has failed, One pen has worked, but a second dose is needed
This should only be attempted once all pens have been tried.

5. Retain any suspected, un-activated pen for reporting to the MHRA via the Yellow Card (further information on page 6) and investigation purposes.

Call for reporting

The reporting of suspected adverse reactions is of great importance. It allows continuous monitoring of the benefit-risk balance of a drug or medical device. Healthcare professionals and patients are encouraged to report any suspected defect or adverse event.

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above)

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

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 the Pharmacovigilance and Medical Information Officer, Tel: 0208 781 5523, Email: Pharmacovigilance.UK@bausch.com

Further information on Emerade including use of the app can be found at https://www.emerade-bausch.co.uk/

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

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