Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Advice for patients with Emerade 500 microgram auto-injectors

According to our records, you have been prescribed Emerade 500 micrograms auto-injector (Emerade pen). The UK's regulator of medicines (Medicines & Healthcare products Regulatory Agency [MHRA]) has received updated information from the company that makes Emerade adrenaline pens.

There is a defect with some Emerade pens. In some cases, the needle is not released, and the injection of adrenaline is not delivered. You may have heard about this previously. You are now being informed that the risk is higher than previously thought. Recent results from tests on unused pens returned by patients indicate that approximately 13% of pens (13 in 100) need higher than normal force to activate. This implies a higher risk of failure to activate than was previously estimated. The earlier tests were conducted on pens that had not been carried by patients but had been stored in the manufacturing facility. The increased risk means it is even more important to follow the advice below.

Most pens will continue to work; carry two pens and use them if you need to
At this time there are not enough adrenaline pens of alternative brands to replace all the Emerade 500 microgram pens held by patients. Most Emerade pens will continue to work. Therefore, the risk to you of being left without any adrenaline from not having a pen is higher than the risk that an Emerade pen you are carrying may not activate. You must always carry two adrenaline pens with you and use them if you need to by following the instructions (see next page). If your first Emerade pen does not activate despite firm pressure, immediately use your second pen. If you are not improving and need a second dose of adrenaline, keep trying to activate a failed Emerade pen while waiting for the ambulance. Further notifications will be issued with immediate effect, as soon as supplies of alternative brands are able to meet the demand for replacement of the remaining Emerade pens held by patients.

Don't expose Emerade pens to heat
No brand of adrenaline pen should be exposed to temperatures higher than 25°C for prolonged periods. Avoiding high temperatures helps to maintain the adrenaline levels within the pen. Separately from this, there is a possibility that exposure to excessively high temperatures may increase the risk of activation failure with Emerade pens. Other causes apart from high heat are possible. However, as a precaution, you should protect your adrenaline pen from heat and do not leave your pen in a hot place (for example, in front of a heater, radiator, or fire.

When your Emerade pen expires, learn how to use your new type of adrenaline pen
When your Emerade pen is due to expire (the end of the month listed on the pen and case), you will be prescribed a different brand of adrenaline pen (EpiPen or Jext). There are some differences between how each brand is used. It is vital that you and the people around you know how to use the pens you have been supplied with.

Ordinarily, your doctor, nurse and pharmacist would be able to help you with training in how to use your new pen. However, we recognise that it may not be possible for you to visit your doctor or pharmacist at the present time. You and those around you must therefore take particular care to read the instructions on how to use your new pen in the leaflet contained in the box. The manufacturers of the different devices also have training information, including videos of how to use them correctly, on their websites. Trainer pens (mock pens that do not contain adrenaline) can also be obtained free of charge via the company websites. You are strongly recommended to order these, and to regularly practise with them. This will make sure you are fully prepared to use your real pen in an emergency. Further information can be found in the Patient Information Leaflets of the different pens and also on the respective manufacturers' websites where training videos are available.

- EpiPen Patient Information Leaflet - https://www.medicines.org.uk/emc/product/4289/pil
- Jext Patient Information Leaflet - https://www.medicines.org.uk/emc/product/5748/pil
- Emerade Patient Information Leaflet - https://www.medicines.org.uk/emc/product/5280/pil

If you have previously been prescribed Emerade 500 microgram, you can be reassured that EpiPen and Jext, both of which are available in a maximum strength of 300 microgram, are safe, effective alternatives to Emerade 500 microgram. You therefore do not need to replace each Emerade 500 microgram pen you used to carry with two 300 microgram EpiPens or 300 microgram Jext pens. You must still carry a total of two pens with you at all times – regardless of strength – in case you need to administer a second dose of adrenaline before the arrival of the emergency services.

What to do if you suspect anaphylaxis

- use your adrenaline pen immediately or ask someone else to do this if you prefer (any person is legally allowed to administer adrenaline to another person to save a life);
- call an ambulance (999) immediately after giving the injection or ask someone to do this. Say this is an emergency case of anaphylaxis (pronounced “anna-fill-axis");
- use your second adrenaline pen 5 to 15 minutes after the first pen if you are not improving or if you start to deteriorate after an initial improvement;
- use your second adrenaline pen immediately if an Emerade pen fails to activate despite pressing firmly against the thigh;
- if you are not improving and need a second dose, keep trying to use a failed Emerade pen while waiting for the ambulance, even if one pen has activated

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, www.mhra.gov.uk/yellowcard. Always include the brand and batch number 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 4) and investigation purposes.

Call for reporting

The reporting of suspected adverse drug reactions (ADRs) 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 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 - www.mhra.gov.uk/yellowcard 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.