Medicines & Healthcare products Regulatory Agency

Advice for patients who have been prescribed an Emerade 500 micrograms or Emerade 300 micrograms auto-injector. Reference: NatPSA/2023/004/MHRA

Emerade Device Recall – due to potential device failure (alternatives available)

- Please contact your doctor or pharmacist (via telephone) now to get replacements for you or your child's Emerade 500 micrograms or Emerade 300 micrograms auto-injector(s) - also referred to as Emerade pen(s).
- 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.
- Once you have two replacement pens in a different brand (EpiPen or Jext), return your Emerade 500 micrograms or Emerade 300 micrograms pen(s) to a pharmacy, even if they are still in date.
- **When you collect your new device make sure you receive training on how to use it. It is vital that you receive training to ensure you are completely familiar with how the new device works.** This is because each brand of adrenaline auto-injector works has a different action.
- Patients should continue to carry two devices at all times.

Reasons for Recall of Emerade Devices

According to our records, you have been prescribed Emerade 500 micrograms or Emerade 300 micrograms auto-injector(s) (adrenaline pen(s)). The UK's regulator of medicines (the Medicines & Healthcare products Regulatory Agency [MHRA]) has received information from the company that makes Emerade adrenaline pens.

Pens were tested and an issue identified where some pens failed to activate as required. As a precautionary measure, all batches of Emerade 500 micrograms and Emerade 300 micrograms pens are being recalled. Therefore, no further supplies will be available of Emerade and patients will need to be switched to an appropriate alternative (EpiPen or Jext).

Replacement of Emerade Devices

You, and/or your parent or carer, should make an urgent appointment with your doctor, or speak to your local pharmacist about replacing the prescription for each Emerade 500 or 300 micograms pen. Ensure that you have two alternative pens of the same brand prescribed.

The alternative pen will be either EpiPen or Jext, both of which are safe and effective in the treatment of anaphylaxis (severe allergic reactions).

Your replacement pens will be either 300 micrograms (0.3 milligram) strength EpiPen or Jext pens, both of which are suitable replacements for a single Emerade 500 micrograms pen. This is based on recently available results from a study, which compared blood levels of adrenaline following injection of Emerade 500 micrograms pens. The study found that there was no difference in results with those following EpiPen 300 micrograms or Jext 300 micrograms pens.

You must continue to always carry two adrenaline pens with you at all times. As soon as you have obtained two new replacement pens you should return all Emerade auto-injector(s) to a local pharmacy.

If you are unwell or unable to collect your prescription because you have been asked to stay at home, please use alternative arrangements to ensure that you receive your new pen(s), such as arranging for a family member to collect the prescription for you.

Training on alternative devices

You and the people around you will need to ensure you know how to use your new EpiPen or Jext pens. These pens work in a different way from Emerade auto-injector pens. Your doctor, nurse or pharmacist can help you with training in how to use your new pen.

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. You should also consult the manufacturer's website for the particular pen you have been supplied with. Training videos on how to use the pens and other information are available on these websites.

- 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

The manufacturers will also provide training pens that do not contain adrenaline. You are strongly recommended to order these, by contacting the manufacturer directly, and practice regularly with them so you are fully prepared for using a real pen in an emergency. Ensure you or your child knows to carry two adrenaline pens at all times.

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 https://www.gov.uk/government/publications/adrenaline-auto-injectors-aais-safety-campaign

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Pictorial guidance – Emerade pen activation troubleshooting

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 instructions 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 9) and investigation purposes.
