Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Advice for patients with an Emerade 300 microgram auto-injector.

- Contact your doctor (via telephone, where appropriate) now to get replacements for you or your child's 300 microgram Emerade auto-injector(s) - also referred to as Emerade pen(s).
- Once you have two replacement pens in a different brand, return your Emerade 300 microgram pen(s) to a pharmacy, even if they are still in date - this should not require someone who is self-isolating to leave their home and pens can be returned at a later date.

According to our records, you or your child has been prescribed Emerade 300 microgram 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 pens about the defect previously reported by the MHRA. The defect means some pens may fail to activate and therefore will not inject adrenaline. 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.

You, and/or your parent or carer, should make an urgent appointment with your doctor. Where possible, telephone appointments should be considered, based on the current UK Government guidelines for self-isolation, social distancing and shielding in relation to Coronavirus (COVID-19) – please follow the advice of your local GP practice/hospital and only attend where you are instructed to do so. Further information can be obtained on the government website: https://www.gov.uk/government/topical-events/coronavirus-covid-19-uk-government-response.

You will need a new prescription to replace each Emerade 300 microgram pen with one new adrenaline pen in an alternative brand up to a total of two adrenaline pens. The alternative pen will be either EpiPen or Jext, both of which are safe and effective in the treatment of anaphylaxis (severe allergic reactions). As soon as you have obtained two new replacement pens you should return your Emerade 300 microgram 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 consider alternative arrangements to ensure that you receive your new pen(s), such as a family member collecting the prescription for you.

You and the people around you will need to ensure you know how to use your new EpiPen or Jext pens. They are used differently from Emerade. Ordinarily, your doctor, nurse or pharmacist would be able 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. 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 website epipen.co.uk and leaflet https://www.medicines.org.uk/emc/product/4290/pil
- Jext website jext.co.uk/ and leaflet https://www.medicines.org.uk/emc/product/5747/pil

The manufacturers will also provide training pens that do not contain adrenaline. You are strongly recommended to order these, and practise regularly with them, so you are fully prepared for use of 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

- 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 pen 5 to 15 minutes after the first pen if you are not improving or if you start to deteriorate after an initial improvement;

You can help us by continuing to report any issues directly via the Yellow Card reporting tool, www.mhra.gov.uk/yellowcard. Always include details of 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 3) 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.