Uppsala May 15 2023

EMERADE PRE-FILLED ADRENALINE PEN: PATIENTS SHOULD REPLACE EMERADE WITH ANOTHER BRAND OF ADRENALINE PEN DUE TO RISK FOR MALFUNCTION

Dear Healthcare professional,

Medeca Pharma AB in agreement with Läkemedelsverket would like to inform you of the following:

- **An error in Emerade adrenaline pens (autoinjector) can potentially cause some pens not to activate as intended OR activate prematurely.**
- **Patients prescribed Emerade adrenaline pens should as soon as possible receive a new prescription for adrenaline pens of another brand.**
- **After receiving an alternative adrenaline pen, it should be ensured that the patient knows how to use it, as each brand of pen works differently.**
- **Until the patients have an adrenaline pen of another brand , they should continue to use their Emerade adrenaline pens in accordance with the product information and instructions from the prescriber.**
- **If an Emerade adrenaline pen fails to activate immediately, an additional attempt should be made using an increased force when pressing the pen against the intended injection site. If the first pen still does not activate, the patient should immediately use their second pen.**
- **If an Emerade adrenaline pen activates prematurely when used to treat an acute allergic reaction, the patient should immediately use their second pen.**

Background

Emerade is currently marketed as 300 and 500 micrograms solutions for injection approved for treating severe acute allergic reactions (anaphylaxis).

In a design assessment study performed by the manufacturer, the results failed to comply with some of the ISO 11608 requirements. The 1.0-meter free-fall (vertical orientation) pre-conditioning resulted in some cases of damage to an internal component of the auto-injector, leading to either failure to activate or premature activation. After pre-conditioning of 30 auto-injectors three (3) failed to activate and one (1) activated prematurely. In these auto-injectors a component involved in initial activation was fractured. This damage was not visibly apparent following the pre-conditioning, but only upon the subsequent functional testing.

In a review of 9 pens returned to the manufacturer during the period 1st January 2020 – 31st March 2023 because of activation force failure complaints, none exhibited broken auto-injector components. One of the eight (8) pre-mature activation complaint samples returned from the market exhibited a fractured component consistent with the failures observed in the ISO testing described above.

Emerade adrenaline pens that are dropped or vigorously handled may fail to activate or may prematurely activate. All Emerade adrenaline pens should therefore as a precaution be replaced as soon as possible. This concerns all strengths and batches of Emerade.

Most Emerade adrenaline pens are, however, expected to function as intended. Until adrenaline pens of another brand are available to the patient, they should continue to use their Emerade adrenaline pens in accordance with the product information and instructions from the prescriber.

When the patients have alternative adrenaline pens available, the Emerade adrenaline pens should be returned to a pharmacy**.**

Call for reporting

Health and care professionals must, according to the national guidelines, report suspect adverse events to Läkemedelsverket (electronic forms and instructions are available at www.lekemedelsverket.se

Company contact point

Fur further information please contact

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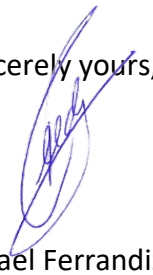
Sincerely yours,



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