LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Emerade
(adrenaline tartrate)

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Summary Public Assessment Report

Emerade

(adrenaline tartrate)

Solution for injection in pre-filled pen - 150 µg, 300 µg, 500 µg

This is a summary of the public assessment report (PAR) for Emerade. It explains how Emerade was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Emerade.

For practical information about using Emerade, patients should read the package leaflet or contact their doctor or pharmacist.

What is Emerade and what is it used for?

Emerade is a 'generic medicine'. This means that Emerade is similar to a 'reference medicine' already authorised in the European Union (EU) called EpiPen.

Emerade is used for emergency treatment of severe allergic reactions (anaphylaxis) caused by allergens in foods, medicines, insect stings or bites and other allergens. It is also used for treatment of severe reactions triggered by exercise or by unknown causes.

How does Emerade work?

Emerade contains adrenaline which counteracts the fall of blood pressure in anaphylactic reactions. It also stimulates the heart and facilitates breathing.

How is Emerade used?

The pharmaceutical form of Emerade is solution for injection in pre-filled pen used for intramuscularly injection in the outer thigh.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Emerade have been shown in studies?

No additional studies were needed as Emerade is a generic medicine that is given by intramuscularly injection and contains the same active substance as the reference medicine, EpiPen.

What are the possible side effects of Emerade?

Because Emerade is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Emerade approved?

It was concluded that, in accordance with EU requirements, Emerade has been shown to have comparable quality and to be similar to the reference medicine EpiPen. Therefore, the Medical Products Agency in Sweden decided that, as for EpiPen, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Emerade?

A risk management plan has been developed to ensure that Emerade is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Emerade, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Emerade

The marketing authorisation for Emerade was granted on 2013-01-10 in Sweden.

The full PAR for Emerade can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Emerade, please read the [package leaflet] or contact your doctor or pharmacist.

This summary was last updated in 2015-08-31.