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Eurneffy(*epinephrine*)

An overview of Eurneffy and why it is authorised in the EU

What is Eurneffy and what is it used for?

Eurneffy is a medicine used for the emergency treatment of allergic reactions (anaphylaxis) caused by insect stings or bites, foods, medicines and other allergens (substances that can cause an allergy) as well as idiopathic (unknown cause) anaphylaxis or anaphylaxis caused by exercise. It is used in adults and children weighing 30 kg or more.

Anaphylaxis is a sudden, severe and sometimes life-threatening allergic reaction that causes a drop in blood pressure and breathing difficulties.

Eurneffy contains the active substance epinephrine (also known as adrenaline).

How is Eurneffy used?

Eurneffy can only be obtained with a prescription and is available as a spray to be given into the nose. Each nasal spray contains a single dose of Eurneffy. Eurneffy is given into one nostril at the first sign of a severe allergic reaction (such as itching of the skin, swelling of the lips, throat or shortness of breath).

Patients should get emergency medical help immediately after using Eurneffy, so that they can be closely monitored and receive further medical treatment if needed.

Patients should always carry two nasal sprays of Eurneffy to treat a severe allergic reaction. If, after the first dose there is no improvement after approximately 10 minutes, or if the symptoms return or worsen, a second dose of Eurneffy should be given in the same nostril together with emergency medical help.

For more information about using Eurneffy, see the package leaflet or contact your doctor or pharmacist.

How does Eurneffy work?

The active substance in Eurneffy is a synthetic (man-made) form of the natural hormone adrenaline, which binds to receptors in cells throughout the body and stimulates different parts of the nervous

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system. A spray of epinephrine into the nose helps to quickly relieve the symptoms of anaphylaxis by narrowing the blood vessels (thereby increasing the blood pressure) and relaxing muscles in the lungs, which opens up the airways to help with breathing.

What benefits of Eurneffy have been shown in studies?

It was not possible to carry out studies on Eurneffy's effectiveness in people experiencing a severe allergic reaction due to ethical and practical reasons. To determine the effectiveness of Eurneffy, data comparing the effects of Eurneffy in the body with those of injectable forms of adrenaline were used. This included data from three studies involving 120 adults who were healthy, had allergies without anaphylaxis or had allergic rhinitis (hay fever) outside of the allergy season and one study involving 21 children weighing 30 kg or more with allergies without anaphylaxis. The studies looked at the effect of Eurneffy on blood pressure and heart rate, as well as at how the medicine is absorbed, modified and removed from the body. The data showed that Eurneffy is well absorbed from the nose and distributes quickly into body tissues. The effects of Eurneffy on the body, as well as how it behaves in the body, are comparable to those of injectable forms of adrenaline.

What are the risks associated with Eurneffy?

For the full list of side effects and restrictions with Eurneffy, see the package leaflet.

The most common side effects with Eurneffy (which may affect more than 1 in 10 people) include throat irritation, headache, nose discomfort and feeling jittery.

Why is Eurneffy authorised in the EU?

The European Medicines Agency considered that Eurneffy is a useful alternative to injectable forms of adrenaline for treating severe allergic reactions. Based on data showing that the effects of Eurneffy in the body, as well as how it behaves in the body, are comparable to those seen with injectable forms of adrenaline, the Agency considered that the medicine is effective for the emergency treatment of allergic reactions. No major safety concerns were identified with Eurneffy. The European Medicines Agency therefore decided that Eurneffy's benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company that markets Eurneffy will provide educational materials for doctors, patients and caregivers with information on how to use the medicine. The company should also provide a training device to healthcare professionals who will prescribe Eurneffy as well as to patients and carers if needed.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Eurneffy have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Eurneffy are continuously monitored. Suspected side effects reported with Eurneffy are carefully evaluated and any necessary action taken to protect patients.

Other information about Eurneffy

Eurneffy received a marketing authorisation valid throughout the EU on 22 August 2024.

Further information on Eurneffy can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Eurneffy.

This overview was last updated in 08-2024.