EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2024
EMA/CHMP/281399/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Eurneffy

epinephrine

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Eurneffy, intended for emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced anaphylaxis. The applicant for this medicinal product is ARS Pharmaceuticals IRL Limited.

Eurneffy will be available as a 2 mg nasal spray solution. The active substance of Eurneffy is epinephrine, an adrenergic and dopaminergic agent cardiac therapy (ATC code: C01CA24). Epinephrine is a non-selective agonist of all adrenergic receptors, including alpha- and beta-adrenergic receptors. Binding to these receptors activates the sympathetic nerve system to minimise vasodilation and vascular permeability that occur during anaphylaxis.

Pharmacokinetic studies with Eurneffy have shown bioavailability of epinephrine after intranasal administration and have shown comparable sympathetic responses to Eurneffy and intramuscular epinephrine injection. The most common side effects are headache, nasal discomfort, throat irritation and feeling jittery.

The full indication is:

> EURneffy is indicated in the emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens as well as idiopathic or exercise induced anaphylaxis. Treatment is indicated for adults and children with a body weight ≥ 30 kg.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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