EURneffy 1 mg approved in the UK as the first and only needle-free adrenaline treatment for young children (aged 4 and older, 15–30 kg) at risk of anaphylaxis

June 15, 2026

ALK announced that the Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorisation for EUR*neffy*® 1 mg, the first and only needle-free adrenaline treatment for anaphylaxis for children aged 4 and older living with severe allergies in the UK – extending a class of treatment previously available only by injection.

EUR*neffy*® 1 mg is now indicated in the UK for the emergency treatment of severe allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products and other allergens, as well as idiopathic or exercise-induced anaphylaxis in children aged 4 years and over weighing 15 kg to less than 30 kg.[1] This approval follows the existing UK marketing authorisation for EUR*neffy*® 2 mg, previously approved by the MHRA for the emergency treatment of anaphylaxis in adults and children weighing ≥30 kg.[1,2]

Anaphylaxis – the most severe, life-threatening form of allergic reaction requiring immediate intervention – affects an estimated 1 to 761 out of every 100,000 children in Europe each year, with food allergies responsible for more than two-thirds of cases.[3-5]
This approval means more people with severe allergies, including children aged 4 years and older who weigh 15 kg to less than 30 kg, will be eligible for treatment with EUR*neffy*®, the only needle-free adrenaline-based product currently approved in the UK.

Flora Beiche-Scholz, EVP Commercial Operations Europe, ALK says:

"*This approval reflects our continued commitment to expanding treatment options for children with severe allergies. For decades, children at risk of anaphylaxis have been limited to injectable adrenaline – yet fear of needles, hesitancy to act and incorrect administration mean adrenaline is too often not carried or used in time. EURneffy® 1 mg aims to address these barriers, offering a needle-free adrenaline solution with the potential to transform the lives of those living with, or caring for, children with severe allergies. This approval brings us closer to ensuring every family affected by severe allergies has a treatment they will actually carry and use*."

Clinical evidence and safety profile

- EUR*neffy*® provides rapid absorption of adrenaline within minutes of administration.[1,2]
- EUR*neffy*® has an established safety profile, based on clinical data from the EUR*neffy*® development programme involving over 700 participants.[2,6]
- The most common adverse reactions in subjects weighing 15 kg to less than 30 kg treated with EUR*neffy*® 1 mg included: nasal congestion (19.0%), upper respiratory tract congestion (14.3%), dry throat, nasal dryness, and paraesthesia (each 9.5%).[7]
- There were no clinically relevant differences in the safety between the paediatric and adult populations treated with EUR*neffy*®.[7]
- EUR*neffy*® 2 mg performed as well as traditional adrenaline auto-injectors or intramuscular adrenaline across a range of real-world scenarios examining the clinical pharmacological effect including single and repeat doses, self-administration, and situations with nasal congestion from allergies.[2,8]
- EUR*neffy*® 1 mg dose demonstrated a comparable absorption and pharmacodynamic effect in children (15-30 kg) as the 2 mg dose in children and adults above 30 kg.[6]

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About EURneffy®
EURneffy® is the first and only needle-free adrenaline-based product approved for the emergency treatment of anaphylaxis in adults and children.[2] EURneffy® is well absorbed through the nose and distributed quickly into body tissues, offering a portable, pocket-sized alternative to injectable forms of adrenaline for treating severe allergic reactions.[2,9] EURneffy® has a total shelf life of 30 months (2 mg) and 24 months (1 mg), no special storage requirements and freezing does not affect its shelf life.[2,10] Upon activation, EURneffy® nasal spray delivers a full, single dose of adrenaline, without the need for priming.[2] It is recommended that two EURneffy® devices are carried to treat a potentially life-threatening emergency in case a second dose is required.[2]

In the UK and European Union, EURneffy® 2 mg is approved for the emergency treatment of anaphylaxis in adults and children who weigh ≥ 30kg, and EURneffy® 1 mg is approved for the emergency treatment of anaphylaxis in children aged 4 and older who weigh from 15 kg to less than 30 kg.[1,2,11,12] In the United States, Japan, China, Australia and Canada EURneffy® 2 mg is approved under the brand name neffy® 2 mg.[13-17] In the US and Australia, neffy® 1 mg has also been approved for children who weigh 15–30 kg (with an age restriction of 4 years and older in Australia) and in Japan, neffy® 1 mg and 2 mg are approved for the emergency treatment of severe allergic reactions (anaphylaxis) in adults and children who weigh

≥15 kg.[10,13]

About anaphylaxis

Anaphylaxis is the most severe form of allergic reaction, characterised by the acute onset of symptoms involving different organ systems, that can occur within minutes of exposure to an allergen, such as insect stings or bites, foods or medicinal products.[3] *It is a serious and potentially life-threatening event requiring immediate medical treatment that can affect babies, children, adults and the elderly.*[18,19] *Globally, the incidence of anaphylaxis is estimated to range from 50 to 112 cases per 100,000 per year, with rates varying more widely in children, from 1 to 761 cases per 100,000 per year.*[4,20] *It is reported that children and adolescents face the highest incidence of anaphylaxis*[21].

Adrenaline is universally recognised as the first-line, life-saving treatment for anaphylaxis, with endorsement across major international guidelines.[3,18,22,23] *Prompt administration is critical to patient outcomes, as delays in treatment are associated with increased morbidity and mortality.*[24,25] *Despite adrenaline's well-established role in anaphylaxis management, AAI use in practice frequently fall short of guideline recommendations.*[26] *Research shows that approximately half of those living with a severe allergy did not administer their AAI when needed in an emergency, and nearly half of those at risk of anaphylaxis do not regularly carry their AAI.*[26,27]

About ALK

ALK is a global specialty pharmaceutical company focused on allergy. ALK's activities cover the entire value chain of developing, sourcing, producing, and marketing a diversified portfolio of products for diagnosing and treating respiratory allergies and severe allergic reactions (anaphylaxis) in both children and adults. Headquartered in Denmark, ALK employs around 2,700 people worldwide and is listed on Nasdaq Copenhagen (Nasdaq: ALK B). Visit us at www.alk.net.

Forward-looking statements

This announcement contains forward-looking statements, including forecasts of future revenue and operating profit as well as expected business-related events. Such statements are naturally subject to risks and uncertainties as various factors, some of which are beyond the control of ALK, may cause actual results and performance to differ materially from the forecasts made in this announcement. Such factors include, but are not limited to, general economic and business-related conditions, including legal issues, uncertainty relating to demand, pricing, reimbursement rules, regulatory approvals, partners' plans and forecasts, fluctuations in exchange rates, competitive factors, and reliance on suppliers. Additional factors include the risks associated with the sourcing and manufacturing of ALK's products. ALK undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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Attachment

- ALK EURneffy 1 mg UK approval press release_FINAL