**EURneffy® UK Prescribing Information**
**Refer to the Summary of Product Characteristics (SmPC) before prescribing**

**Name.** EURneffy® 2 mg adrenaline nasal spray, solution in single-dose container
**Qualitative and Quantitative Composition**. Each single-dose container delivers adrenaline (epinephrine) 2 mg in 100 microlitres. Nasal spray, solution. The solution is clear and colourless to pink brownish. A solution with a pH of 3.0-5.5 and an osmolality of 325–560 mOsm/kg. Excipients with known effect are: Benzalkonium chloride, 40 micrograms per single-dose container. Sodium metabisulfite 5 micrograms, per single-dose container.
**Indication.** 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.
**Dosage, method of use and route of administration.** For nasal use only. This medicinal product is a ready-to-use, nasal spray, solution in single-dose container. It delivers its entire dose upon activation. The nasal spray should not be primed and should not be sprayed in the eyes or mouth. This medicinal product is for single use only and must be discarded and replaced immediately after use as it delivers only one dose. The recommended initial dose is a single nasal administration of 2 mg adrenaline. A dose of 2 mg by nasal administration results in adrenaline plasma concentrations that are within the overall range of exposures observed with devices that deliver 0.3 mg of adrenaline by intramuscular injection in the thigh.
Patients and caregivers should be counselled to carefully read the instructions for use in the package leaflet for complete directions on how to properly administer this medicinal product. The patient/caregiver should be informed to seek emergency medical assistance immediately to have close monitoring of the anaphylactic episode and in the event further treatment is required. In the absence of clinical improvement after 5 minutes, or if deterioration occurs or symptoms reappear after the initial treatment, a second dose should be administered in the same nostril. A maximum of 4 mg (two doses) may be given unless instructed by a medical professional to give additional doses. It is recommended that patients should always carry two nasal sprays to treat an allergy emergency. If a second dose is needed but not available, seek emergency medical assistance immediately. Patients should preferably lie flat with feet elevated, but sit up if they have breathing difficulties. Patients should not stand up even if someone encourages them to, and should not suddenly change position. Patients should stay lying down even if they feel better. Unconscious patients should be placed on their side in a recovery position. Pregnant women should lie on their left side.
**Contraindications.** None.
**Special warnings and precautions for use.** All patients who are prescribed this medicinal product should be clearly instructed on how and when to use the product. For children under 12 years of age, the caregiver should administer EURneffy® or determine that the child is properly instructed in the use of EURneffy® and is fully capable of administration themselves. Patients with a cold or a congested nose can use this medicinal product, even in these conditions, however the PK profile may be different. Patients should be instructed to recognise symptoms of severe allergic reactions and anaphylaxis that may occur within minutes after exposure and which may consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhoea and abdominal cramps, involuntary voiding, wheezing, dyspnoea due to laryngeal spasm, pruritus, rashes, urticaria, or angioedema. Patients with concomitant asthma may be at increased risk of severe anaphylactic reaction. Adrenaline is recommended for use at first signs or symptoms of severe allergic reactions leading to anaphylaxis. Patients should be instructed to always carry adrenaline in situations of potential risks. The patient/caregiver should be informed about the possibility of biphasic

anaphylaxis which is characterised by initial resolution followed by recurrence of symptoms some hours later.
**Interactions**. Extreme caution should be taken when administering adrenaline to patients who have a heart disease. Caution is indicated in patients receiving medicinal products that may sensitise the heart to arrhythmias, including digoxin, mercurial diuretics (e.g. chlormerodrin, merbaphen, mersalyl acid, meralluride, mercaptomerin, mercurophylline, merethoxylline procaine) or quinidine. The effects of adrenaline may be potentiated by tricyclic antidepressants (e.g. imipramine) and mono amine oxidase inhibitors (MAO-inhibitors) (e.g. isocarboxazid, phenelzine, selegiline, tranylcypromine) and catechol-O-methyl transferase inhibitors (COMT-inhibitors) (e.g. entacapone, tolcapone, carbidopa-levodopa-entacapone, opicapone), thyroid hormones, theophylline, oxytocin, parasympatholytics (e.g. atropine, cyclopentolate, homatropine, hyoscine, tropicaminde), certain antihistamines (diphenhydramine, chlorpheniramine), levodopa, and alcohol. Pressor effects of adrenaline may be counteracted by rapidly acting vasodilators or alpha-adrenergic-blocking medicinal products such as phentolamine. Adrenaline inhibits the secretion of insulin, thus increasing the blood glucose level. It is unlikely if given in an acute emergency situation that adrenaline would have any persistent effect on blood glucose levels, but for diabetic patients receiving adrenaline it may be necessary to increase their dose of insulin or oral hypoglycaemic medicinal products. The beta-stimulating effect of adrenaline may be inhibited by simultaneous treatment with beta-blocking medicinal products, e.g. propanolol. There are no data on the effect of EURneffy® in pregnant women. The use of this medicinal product may be considered during pregnancy, if necessary. There are no data on the effect of adrenaline in breastfeeding women. However, EURneffy® can be used in breastfeeding women. A risk to the newborns/infants cannot be excluded. However, due to its poor oral bioavailability and short half-life, exposure is expected to be very low in the breastfed infants.
**Undesirable effects** The most frequently occurring adverse reactions (very common events ≥ 10%) observed in clinical studies of EURneffy® were reported only after second 2 mg dose (4 mg total) and include throat irritation (18.8%), headache (17.6%), nasal discomfort (12.9%) and feeling jittery (10.6%). None of the adverse drug reactions observed in the clinical studies were serious. Common (⩾ 1/100 to < 1/10): anxiety, tremor, palpitations, rhinorrhoea, nasal oedema, rhinalgia, nasal congestion, blood pressure increased and heart rate increase. **Consult the SmPC for details of adverse reactions. Overdose** Overdose of adrenaline may cause severe headaches, chest pain, dizziness, nausea, and blurred vision. Significant overdoses or injection into a blood vessel can also cause cerebral haemorrhage resulting from a sharp rise in blood pressure. Fatalities may also result from pulmonary oedema because of peripheral vascular constriction together with cardiac stimulation. Prescribers should consult the summary of product characteristics in relation to other adverse reactions.
**Special Precautions for Storage** Shelf life: 30 months. This medicinal product does not require any special storage conditions. If accidentally frozen, the nasal spray will not function. Allow the nasal spray to thaw at least one hour; do not use if the contents are still frozen or not completely thawed. Freezing does not affect the shelf life of the product.
**Legal Categorisation** POM
**Marketing Authorisation Number** PL10085/0060
**Marketing Authorisation holder:** ALK-Abelló A/S, Bøge Allé 6-8, 2970 Hørsholm, Denmark
**Basic NHS cost** please state cost
**Date of last revision** please add date last revised, when finalised

**Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to ALK-Abelló Ltd at drugsafetyuk@alk.net.**