ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

EURneffy 2 mg nasal spray, solution in single-dose container

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single-dose container delivers adrenaline (epinephrine) 2 mg in 100 microlitres

Excipients with known effect

Benzalkonium chloride 40 micrograms per single-dose container.
Sodium metabisulfite 5 micrograms per single-dose container.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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.

4.2 Posology and method of administration

Posology

This medicinal product should be administered at the first sign of a severe Type I allergic reaction.

The recommended initial dose is a single nasal administration of 2 mg adrenaline.

The patient should be advised to immediately seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.

In the absence of clinical improvement after approximately 10 minutes, or if deterioration occurs or symptoms reappear after the initial treatment, a second dose should be administered in the same nostril together with emergency medical help. 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.

Elderly
No pharmacokinetic data are available after nasal administration of adrenaline in patients aged 65 years or older. No dose adjustment is required.

Paediatric population
The recommended posology in children with a body weight ≥ 30 kg is the same as adults.

The safety and efficacy of EURneffy in children below 30 kg body weight has not been established. No data are available.

Method 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.

Instructions for administration
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 (see section 4.4).

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.

- If symptoms get worse or reoccur after approximately 10 minutes, or if any error in dosing is suspected, a new nasal spray should be used to give a second dose in the same nostril.
- 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. Unconscious patients should be placed on their side in a recovery position.

For full instructions on the use of the medicinal product, see section 6.6.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

Instructions for patients at the time of prescribing

A physician who prescribes this medicinal product should take appropriate steps to ensure that the patient understands the indication and use of the nasal spray thoroughly. The physician should review the patient information leaflet and operating instructions of the nasal spray with the patient. All patients who are prescribed this medicinal product should be clearly instructed on how and when to use the product (see section 4.2). It is strongly advised to also educate the patient's immediate associates (e.g., parents, caregivers, teachers) on the correct use of this medicinal product in case support is needed in an emergency.

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 pharmacokinetic profile may be different (see section 5.2).

Warnings for patients about anaphylaxis

Patients should be instructed to recognise symptoms of systemic 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 allergy events 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. The patient should be advised to always seek medical assistance immediately after any severe allergic reaction.

Populations at increased risks with the use of adrenaline

Extreme caution should be taken when administering adrenaline to patients who have a heart disease.

Use of adrenaline with medicinal products that may sensitise the heart to arrhythmias, e.g., digoxin, mercurial diuretics, or quinidine, ordinarily is not recommended (see section 4.5). Anginal pain may be induced by adrenaline in patients with coronary insufficiency.

There is a risk of adverse reactions following adrenaline administration in patients with high intraocular pressure, severe renal impairment, prostatic adenoma leading to residual urine, hypercalcaemia, and hypokalaemia. In patients with Parkinson's disease, adrenaline may be associated with a transient worsening of Parkinson's symptoms such as rigidity and tremor.

Individuals with hyperthyroidism, cardiovascular disease, hypertension, or diabetes, elderly individuals, and pregnant women may be at greater risk of developing adverse reactions after adrenaline administration (see sections 4.6 and 4.8).

Patients with these conditions, and/or any other persons who might be in a position to administer this medicinal product to a patient experiencing a severe allergic reaction or anaphylaxis should be carefully instructed in regard to the circumstances under which this life-saving medicinal product should be used.

Excipients with known effect

Benzalkonium chloride
This medicinal product contains benzalkonium chloride that may cause irritation or swelling inside the nose, especially if used for a long time.

Sodium metabisulphite
This medicinal product contains metabisulphite that may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

Adrenaline and other medicinal products

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

Pressor effects of adrenaline may be counteracted by rapidly acting vasodilators or alpha-adrenergic-blocking medicinal products such as phentolamine.

Adrenaline and insulin

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.

Adrenaline and beta-blocking medicinal products

The beta-stimulating effect of adrenaline may be inhibited by simultaneous treatment with beta-blocking medicinal products, e.g. propanolol.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data on the effect of EURneffy in pregnant women.

A moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicates no malformation or feto/ neonatal toxicity of adrenaline. While an endogenous substance and blood levels after administration of EURneffy are within normal physiologic ranges, adrenaline increases blood pressure and heart rate which can impact the foetus.

Animal studies do not indicate reproductive toxicity (see section 5.3).

The use of this medicinal product may be considered during pregnancy, if necessary.

Breast-feeding

There are no data on the effect of adrenaline in breast-feeding mothers. However, EURneffy can be used in breast-feeding mothers.

It is unknown whether adrenaline/ metabolites are excreted in human milk.

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.

Fertility

There are no data on the effect of EURneffy on human fertility.

Adrenaline is an endogenous substance and blood levels after administration of EURneffy are within normal physiological ranges and as such it is unlikely that there would be any detrimental effects on fertility.

4.7 Effects on ability to drive and use machines

EURneffy has no or negligible influence on the ability to drive and use machines. It is not recommended that patients who are suffering an anaphylactic reaction drive or use machines because of the anaphylactic reaction.

4.8 Undesirable effects

Summary of safety profile

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.

Tabulated list of adverse reactions

Adverse reactions are summarized based on analysis of pooled safety data from primary PK/PD studies using EURneffy 2 mg in adult healthy volunteers, in patients with Type 1 allergies and in patients with allergic rhinitis. The adverse reactions are ranked according to system organ class and frequency according to the following convention:

- Very common (≥ 1/10)
- Common (≥ 1/100 to < 1/10)
- Uncommon (≥ 1/1 000 to < 1/100)
- Rare (≥ 1/10 000 to < 1/1 000)
- Very rare (< 1/10 000)
- Not known (frequency cannot be estimated from the available data)

Table 1: Adverse drug reactions identified with EURneffy

System organ class	Frequency	Adverse reaction
Psychiatric disorders	Common	Anxiety
	Uncommon	Euphoric mood Nervousness
	Not known	Disorientation[1] Memory impairment[1] Panic reaction[1]
Nervous system disorders	Very Common	Headache
	Common	Tremor
	Uncommon	Dizziness Paraesthesia Head discomfort Presyncope
	Not known	Psychomotor hyperactivity[1] Somnolence[1]
Eye disorders	Uncommon	Lacrimation increased
Cardiac disorders	Common	Palpitations
	Not known	Angina[1] Cardiac arrhythmias[1,2] Stress cardiomyopathy[1] Tachyarrhythmia[1] Tachycardia[1] Ventricular ectopy[1]
Vascular disorders	Not known	Hypertension[1] Vasoconstriction[1]
Respiratory, thoracic and mediastinal disorders	Very Common	Nasal discomfort Throat irritation
	Common	Rhinorrhoea Nasal oedema Rhinalgia Nasal congestion

System organ class	Frequency	Adverse reaction
	Uncommon	Oropharyngeal pain Nasal pruritus Sneezing Intranasal paraesthesia Paranasal sinus discomfort Epistaxis Nasal dryness Nasal mucosal disorder
Gastrointestinal disorders	Uncommon	Nausea Paresthesia oral Salivary hypersecretion Toothache Gingival discomfort
Skin and subcutaneous tissue disorders	Uncommon	Pruritus
	Not known	Paraesthesia[1]
General disorders and administration site conditions	Very Common	Feeling jittery
	Uncommon	Chest discomfort Energy increased Fatigue Feeling hot
Investigations	Common	Blood pressure increased Heart rate increased
	Uncommon	Body temperature increased

[1] Adverse reactions that have not been observed in clinical studies with EURneffy, but are known to occur with other adrenaline formulations including intravenous, intramuscular, and subcutaneous administrations.
[2] Cardiac arrhythmias may follow administration of adrenaline (see section 4.4).

Paediatric population

In a clinical trial of paediatric subjects, 16 subjects between 8 and 17 years of age weighing more than 30 kg were treated with EURneffy 2 mg. The most common adverse reactions included: nasal discomfort and intranasal paraesthesia (25.0%); sneezing (18.8%); fatigue, feeling jittery, paraesthesia, rhinalgia, and rhinorrhoea (12.5%); and epistaxis, lacrimation increased, oropharyngeal pain, and pharyngeal paraesthesia (6.3%).

There were no clinically relevant differences in the safety between the paediatric and adult populations treated with EURneffy 2 mg.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Symptoms

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.

Management

Pressor effects of adrenaline may be counteracted by rapidly acting vasodilators or alpha-adrenergic blocking medicinal products.

If an adrenaline overdose induces pulmonary oedema that interferes with respiration, treatment consists of a rapidly acting alpha-adrenergic blocking medicinal product such as phentolamine and/or intermittent positive-pressure respiration.

Adrenaline overdose can cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Treatment of arrhythmias may consist of administration of beta-adrenergic blocking medicinal products.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cardiac therapy, adrenergic and dopaminergic agents
ATC code: C01CA24

Mechanism of action

Adrenaline is a nonselective agonist of all adrenergic receptors, including alpha- and beta-adrenergic receptors. Binding to these receptors triggers a number of actions of sympathetic nerve system.

Pharmacodynamic effects

Through its action on alpha-adrenergic receptors, adrenaline lessens histamine induced vasodilation. Adrenaline also reduces the vascular permeability induced by histamine that occurs during anaphylaxis.

Adrenaline, through its action on beta-adrenergic receptors in bronchial smooth muscle, causes bronchial smooth muscle relaxation.

Adrenaline also alleviates pruritus, urticaria, and angioedema and may be effective in relieving gastrointestinal and genitourinary symptoms associated with anaphylaxis.

Clinical efficacy

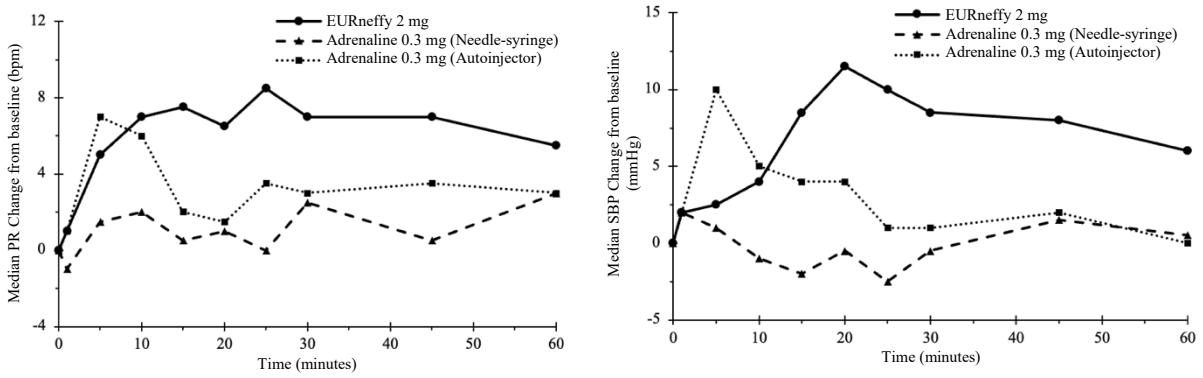
Four clinical pharmacology studies of EURneffy in adults and one clinical pharmacology study in pediatric subjects who weigh 30 kg or greater are described below.

Systolic blood pressure and pulse rate in healthy adult subjects (Study EPI 15)
Study EPI 15 was conducted in healthy adult subjects (N=42) that compared the pharmacokinetics (PK) and pharmacodynamics (PD) (i.e., pulse rate (PR) and systolic blood pressure (SBP)) of adrenaline following:

- One nasal dose of EURneffy 2 mg to one intramuscular dose of adrenaline injection 0.3 mg (using a needle-syringe product and an auto-injector product).
- Two nasal doses of EURneffy 2 mg, administered 10 minutes apart, into either same naris or opposite nares to two intramuscular doses of adrenaline injection 0.3 mg (using an auto-injector) administered 10 minutes apart.

Results following one dose of all adrenaline products demonstrated an increase from baseline SBP and PR as shown in Figure 1.

Figure 1: Median pulse rate (PR) and systolic blood pressure (SBP) change from baseline following one dose of adrenaline in healthy subjects [Study EPI 15]



Results following two nasal doses of EURneffy (in the same naris or opposite nares) in comparison to two intramuscular doses of adrenaline injection (using an autoinjector) showed a similar trend in median/mean SBP and PR responses.

Systolic blood pressure and pulse rate in adult patients with Type I allergy without anaphylaxis (Study EPI 17)
Study EPI 17 was conducted in adult patients with type I allergy without anaphylaxis (N=42) that compared the PK and PD of adrenaline following self-administered one nasal dose of EURneffy 2 mg to staff-administered one intramuscular dose of adrenaline injection 0.3 mg (using a needle-syringe product). In Study EPI 17, SBP and PR responses were assessed as a change from baseline over 60 minutes. The SBP and PR responses results in Study EPI 17 were similar to Study EPI 15.

Systolic blood pressure and pulse rate in adult patients with allergic rhinitis (Study EPI 16 and EPI 18)
Study EPI 16 and Study EPI 18 were conducted in adult subjects with seasonal allergic rhinitis outside of allergy season. Subjects were required to have seasonal allergic rhinitis which was confirmed with a nasal allergen challenge (NAC) during screening and did not have any allergy symptoms prior to treatment. Allergic rhinitis symptoms were induced by spraying the known allergen into the subject's nostrils in which a minimum Total Nasal Symptom Score (TNSS) of ≥ 5 out of 12, with a congestion component of ≥ 2 out of 3 had to be reached.

Study EPI 16 enrolled 36 subjects. In this cross-over study, subjects received adrenaline as each of the following:

- One nasal dose of EURneffy 2 mg without nasal allergen challenge (NAC).
- One nasal dose of EURneffy 2 mg after undergoing NAC to induce rhinitis/nasal congestion.
- One intramuscular dose of adrenaline injection 0.3 mg (using a needle syringe) without NAC.
- One intramuscular dose of adrenaline injection 0.5 mg (using a needle syringe) without NAC.

In Study EPI 16, SBP and PR responses were assessed as a change from baseline over 60 minutes. Results showed the following:

- Median SBP and PR for EURneffy with NAC initially increased from baseline, but the median responses were lower than the use of EURneffy without NAC after 5 to 15 minutes post-dose.
- Median SBP response for EURneffy with NAC was initially higher than the median SBP response for the intramuscular adrenaline injection without NAC through 20 minutes, after which the median SBP response for EURneffy with NAC became comparable to the adrenaline injection without NAC through 60 minutes post-dose.

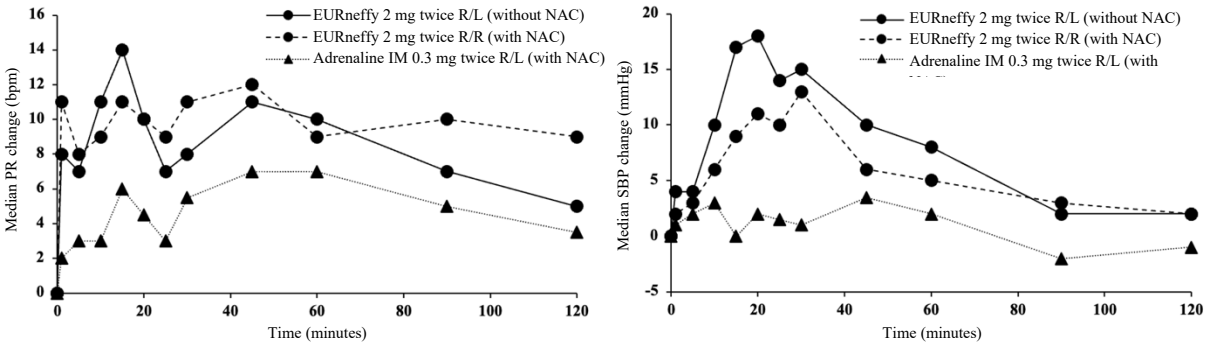
- Median PR response for EURneffy with NAC was initially higher than adrenaline injection without NAC during the first 5 minutes post-dose, but then was numerically lower than the median PR response for adrenaline injection without NAC through 60 minutes post-dose.

Study EPI 18 enrolled 43 subjects. In this cross-over study, subjects received two doses of adrenaline administered 10 minutes apart as each of the following:

- Two nasal doses of EURneffy 2 mg (in the opposite nares (right(R)/left (L)) without NAC.
- Two intramuscular (IM) doses of adrenaline injections 0.3 mg (using a needle-syringe; in the opposite thigh (R/L)) without NAC.
- Two nasal doses of EURneffy 2 mg (either in the same naris (R/R) or opposite nares (R/L)) after NAC to induce allergic rhinitis/nasal congestion.
- Two intramuscular doses of adrenaline injections 0.3 mg (using a needle-syringe; in the opposite thigh (R/L)) after NAC to induce allergic rhinitis/nasal congestion.

In Study EPI 18, SBP and PR responses were assessed as a change from baseline over 60 minutes. Results showed the following:

Figure 2: Median change from baseline for systolic blood pressure (SBP) and pulse rate (PR) following two doses of adrenaline administered 10 minutes apart in right and left nares (R/L) or right and right nares (R/R) in subjects with allergic rhinitis with and without nasal allergen challenge (NAC) [Study EPI 18]



Paediatric population

Systolic blood pressure and pulse rate in pediatric patients with type I allergy without anaphylaxis (Study EPI 10)

Study EPI 10 was a single-arm study conducted in pediatric patients who weighed 30 kg or greater (age range: 8 to 17 years) with type I allergy without anaphylaxis (N=21) that assessed the PK and PD of adrenaline following one nasal dose of EURneffy 2 mg. The median change in SBP and PR from baseline over the 60 minutes post-dose were numerically lower than in healthy adults who received the same dose of EURneffy in Study EPI 15.

The European Medicines Agency has deferred the obligation to submit the results of studies with EURneffy in one or more subsets of the paediatric population in the treatment of allergic reactions (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Absorption

Following one nasal dose of EURneffy 2 mg, the geometric mean plasma adrenaline concentration-time profile was overall within the range of that following one intramuscular dose of adrenaline

injection 0.3 mg (using a needle-syringe product and an auto-injector product) 60 minutes post-dose. The integrated pharmacokinetic parameters of adrenaline are summarized in Table 2.

Table 2: Mean (CV%) and geometric mean plasma PK parameters following one or two doses of adrenaline (integrated analysis)

Treatment	N	t_{max} (min) median (range)	C_{max} (pg/mL)		AUC_{last} (min*pg/mL)	
			Mean(%CV)	Geo.mean	Mean(%CV)	Geo.mean
EURneffy 2 mg IN (HCP administration)	78	20.5 (2 - 150)	485 (70.6)	361	40900 (67.5)	32600
EURneffy 2 mg IN (self-administration)	32	30 (10 - 240)	448 (67.1)	342	50365 (55.5)	41077
EURneffy 2 mg IN (pediatrics)	16	25.0 (2.5 - 120)	540 (70.7)	433	35500 (76.3)	27800
EURneffy 2 mg twice (L/R)	39	30 (6 - 150)	1000 (93.1)	706	86000 (77)	66700
EURneffy 2 mg twice (R/R)	39	30 (4 - 150)	992 (75.3)	729	86500 (60.5)	69900
Adrenaline 0.3 mg IM	178	45 (3.9 -360)	277 (65.4)	234	27900 (38.7)	26100
Adrenaline 0.3 mg IM twice	70	45 (6 - 180)	436 (48.8)	386	47500 (32.6)	45300
EpiPen 0.3 mg	77	10 (2 - 45)	581 (75.6)	447	31600 (39.3)	29200
EpiPen 0.3 mg twice	78	20 (4 - 360)	754 (64.7)	630	55000 (47.9)	29200

IN: intranasal; IM: intramuscular

Adrenaline has a rapid onset of action after administration. Following nasal administration to healthy volunteers, adrenaline was rapidly absorbed after both single and repeat dosing, with a time to maximum plasma concentration in 20 to 30 minutes. In subjects with rhinitis (congestion and nasal oedema), adrenaline is absorbed more rapidly with the maximum concentration observed in about 10 minutes.

Biotransformation

Adrenaline is rapidly inactivated in the body, mostly in the liver by the enzymes catechol-O-methyltransferase (COMT) and monoamine oxidase (MAO).

Elimination

Much of a dose of adrenaline is excreted as metabolites in urine. Elimination is mainly via metabolism of the liver and sympathetic nerve endings, with a small amount excreted unchanged in the urine. The plasma half-life following nasal administration is about 2 to 3 minutes.

Paediatric population

Pediatric patients with type I allergies without anaphylaxis (Study EPI 10)
In pediatric patients with Type I allergies weighing 30 kg or greater (age range: 8 to 17 years), following a single 2 mg nasal dose of EURneffy, the geometric mean plasma adrenaline concentration time profile was similar to that of healthy adults receiving the same dose within about 15 minutes post-dose (in a different study) and then became slightly higher than that of healthy adults (see Table 2).

5.3 Preclinical safety data

Nonclinical data carried out on EURneffy formulation and on adrenaline based on scientific literature, reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Dodecylmaltoside
Disodium edetate
Benzalkonium chloride
Sodium metabisulphite (E 223)
Hydrochloric acid, concentrated (for pH-adjustment)
Sodium hydroxide (for pH-adjustment)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

Type I glass vials and closed with a grey bromobutyl rubber stopper and then assembled into a Unit Dose Sprayer (UDS) device. The device is a non-pressurized dispenser delivering a single-dose nasal spray.

Pack size: Pack of 2 single-dose nasal sprays
Pack of 1 single-dose nasal spray

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Instructions for use

A: To administer, the nasal spray should be removed from the packaging, by pulling open the packaging (see figure 1A).

(Figure 1A)

B: Hold the nasal spray with your thumb on the bottom of the plunger and a finger on either side of the nozzle (see figure 1B).

- Do not pull or push on the plunger.
- Do not test or pre-spray; each nasal spray has only one dose.

(Figure 1B)

C: Insert tip of nasal spray into a nostril until your fingers touch your nose (see figure 1C).

- Keep the nozzle straight into the nose pointed toward your forehead.
- Do not angle the nasal spray to the inner or outer walls of the nose

(Figure 1C)

D: Press plunger up firmly until it snaps up and sprays into the nostril (see figure 1D).

(Figure 1D)

Do Not:

Do not angle the nasal spray to the inner or outer walls of the nose.

Seek emergency medical assistance immediately to have close monitoring of the anaphylactic episode and in the event further treatment is required.

If symptoms continue to worsen or reoccur after approximately 10 minutes, or of any error in administration, use a new EURneffy nasal spray to give a second dose in the same nostril as the first dose and seek urgent emergency medical assistance.

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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

ARS Pharmaceuticals IRL, Limited
The Black Church
Saint Mary's Place North
Dublin 7
Co. Dublin
D07 P4AX
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1846/001
EU/1/24/1846/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 August 2024

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency https://www.ema.europa.eu

ANNEX II

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Tiofarma B.V.
Hermanus Boerhaavestraat 1
3261 ME Oud-Beijerland
The Netherlands

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

- **Additional risk minimisation measures**

Prior to the launch of EURneffy in each Member State the Marketing Authorisation Holder (MAH) must agree about the content and format of the educational programme, including communication media, distribution modalities, and any other aspects of the programme, with the National Competent Authority.

The educational programme is aimed at preventing misuse of the medicinal product in the context of an emergency situation.

The MAH shall ensure that in each Member State where EURneffy is marketed, all healthcare professionals and patients/carers who are expected to prescribe, dispense, use EURneffy have access to/are provided with the following educational information:

- Physician educational material
- Patient/caregivers information pack

Physician educational material:

- The Summary of Product Characteristics
- Training device
- Healthcare professionals training material (training videos)
    - Training device to familiarise with use of EURneffy device
    - Indications in which EURneffy should be used
    - Detailed description of the administration procedures of EURneffy
    - Importance of seeking medical assistance when using EURneffy
    - Relevant information on the EURneffy single dose device and how to use it
    - Instructions on correct handling of EURneffy device
    - Need to always carry a second device in case of second dose would be required
    - Need to seek emergency medical assistance
    - Patient's preparation for the procedure and subsequent monitoring
    - Management of early signs and symptoms of selected safety concerns, namely severe allergic reaction/anaphylaxis

Patient/caregivers information pack:

- Patient information leaflet
- Training device provided by physician as needed
- The patient/caregivers /digital information brochure/videos:
    - Indication in which EURneffy should be used including anaphylaxis/severe allergic reaction action plan
    - Information on how to identify a serious allergic reaction
    - A description of the correct use of Eurneffy and the need to seek emergency medical assistance when using EURneffy
    - Detailed description of the modalities used for the self-administration of EURneffy
    - A description of the best course of action if second dose is needed
    - Need to always carry a second device in case of second dose would be required
    - Monitoring and guidance for actions following use of EURneffy

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE CARTON

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

EURneffy 2 mg nasal spray, solution in single-dose container
adrenaline

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each single-dose container delivers 2 mg adrenaline in 100 microlitres.

3. LIST OF EXCIPIENTS

Contains sodium metabisulphite and benzalkonium chloride

4. PHARMACEUTICAL FORM AND CONTENTS

nasal spray, solution

2 single-dose nasal sprays
1 single-dose nasal spray

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For nasal use only.
Single use
Read package leaflet before use

QR code + eurneffy.eu
Scan to Learn More

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of sight and reach of children who are not the intended user.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

ARS Pharmaceuticals IRL, Limited
The Black Church, St Mary's Place,
Dublin, D07 P4AX, Ireland

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/24/1846/001
EU/1/24/1846/002

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

Seek emergency medical assistance immediately to have close monitoring of the anaphylactic episode and in the event further treatment is required.

16. INFORMATION IN BRAILLE

EURneffy 2 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS/ STRIPS

TRAY

1. NAME OF THE MEDICINAL PRODUCT

EURneffy 2 mg
nasal spray, solution in single-dose container
adrenaline

2. NAME OF THE MARKETING AUTHORISATION HOLDER

ARS Pharmaceuticals, IRL, Limited.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

For nasal use only.
Single use.

Read the package leaflet before use.

QR code + eurneffy.eu
Learn More

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NASAL SPRAY

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

EURneffy 2 mg nasal spray
adrenaline
For nasal use only

2. METHOD OF ADMINISTRATION

Single use

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

2 mg

6. OTHER

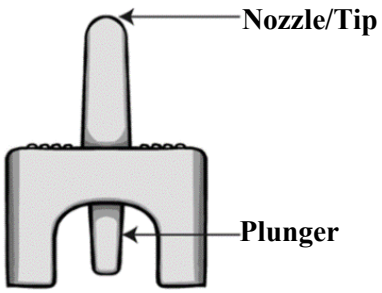
Intructions for use to be included within blister pack

Instructions for use
EURneffy® 2 mg nasal spray, solution in single-dose container
adrenaline

Before you need to use it, fully familiarise yourself with EURneffy, including when and how it should be used.

EURneffy 2 mg nasal spray

EURneffy 2 mg nasal spray:



Follow these instructions only when ready to use.

A

Remove EURneffy 2 mg nasal spray from packaging.
Pull open the packaging to remove the EURneffy 2 mg nasal spray.

B

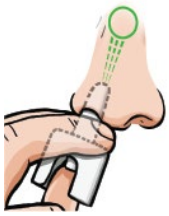
Hold the nasal spray as shown.
Hold the nasal spray with your thumb on the bottom of the plunger and one finger on either side of the nozzle.

- **Do not pull or push on the plunger**
- **Do not test or pre-spray; each nasal spray has only one dose.**

C

Insert tip of nasal spray into a nostril until your fingers touch your nose.
Keep the nozzle straight into the nose pointed toward your forehead.
Do not angle the sprayer to the inner or outer walls of the nose.

D



Press plunger up firmly until it snaps up and sprays into the nostril.

Do not angle the nasal spray to the inner or outer walls of the nose.

Seek emergency medical assistance

Seek emergency medical assistance immediately to have close monitoring of the anaphylactic episode and in the event further treatment is required.

Monitor patient symptoms

If symptoms continue to worsen or reoccur after approximately 10 minutes, or if any dosing error, give a second dose using a new EURneffy nasal spray in the SAME nostril as the first dose and seek urgent emergency medical assistance.

If necessary, you can lie down with feet raised. If this makes you breathless, you should sit up. Unconscious patients should be placed on their side in the recovery position. If symptoms do not resolve, you should, if possible, remain with another person until medical assistance arrives.

B. PACKAGE LEAFLET

Package leaflet: Information for the user

EURneffy 2 mg nasal spray, solution in single-dose container
adrenaline

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What EURneffy is and what it is used for

EURneffy contains the active substance adrenaline (epinephrine) which is an adrenergic medicine (medicine that has an effect on the sympathetic nervous system, the part of the nervous system that increases heart rate, blood pressure, breathing rate, and pupil size).

EURneffy is used in adults and children with a body weight of 30 kg or more for the emergency treatment of allergic reactions, including anaphylaxis (sudden, severe and sometimes life-threatening allergic reactions), to insect stings or bites, foods, medicines and other allergens (substances that cause an allergy) as well as idiopathic anaphylaxis (the cause of anaphylaxis is not known) or anaphylaxis caused by exercise. EURneffy is intended for immediate self-administration by a person (or given to a person by a caregiver or medical professional) with a history or recognised risk of a severe allergic reaction that can lead to anaphylactic shock.

The active substance in EURneffy, adrenaline, is a naturally occurring hormone released by the body in response to stress. It works directly on the cardiovascular (heart and blood circulation) and respiratory (lung) systems to stop the possible fatal effects of a severe allergic reaction that can lead to anaphylactic shock. In acute allergic reactions it improves blood pressure, heart function and breathing, and reduces tissue swelling.

EURneffy is an emergency rescue therapy but you must seek emergency medical assistance immediately to have close monitoring of the anaphylactic episode and in the event further treatment is required. Always tell your friends and family that you carry EURneffy with you (see section 2 Warnings and precautions).

2. What you need to know before you use EURneffy

Do not use EURneffy
There is no known reason why anyone should not use EURneffy during an allergic emergency.

Warnings and precautions

You, or anyone who may need to give EURneffy to you (such as a parent, caregiver or teacher), should be carefully instructed by your doctor or nurse on how and when to correctly use EURneffy (see the instructions for use in section 3 “How to use EURneffy”).

Symptoms that signal the onset of an anaphylactic shock occur within minutes of exposure to the allergen and include: itching of the skin; raised rash (like a nettle rash); flushing; swelling of the lips, throat, tongue, hands and feet; wheezing; hoarseness; shortness of breath; nausea; vomiting; stomach cramps and; in some cases, loss of consciousness; apprehension, a fast heartbeat, fitting, diarrhoea (loose stools), loss of bladder control. Use EURneffy at the first signs or symptoms of a severe allergic reaction.

Symptoms of anaphylaxis can reoccur within 72 hours of the initial episode, even without new exposure to the allergen that triggered the allergic reaction.

You must make sure you understand the reason EURneffy has been prescribed for you. You should be confident that you know exactly how and when to use EURneffy. Explain how to use EURneffy to your family, carers, co-workers or teachers. They will need to know how to use it before you suffer an anaphylactic reaction.

If you are at risk of a severe allergic reaction, you should always keep EURneffy with you.
Patients with a history or a recognised risk of a severe allergic reaction that can lead to anaphylactic shock should have quick access to EURneffy.

If you have asthma, you may be at increased risk of a severe allergic reaction.

Anyone who has an episode of anaphylaxis should see their doctor about testing for substances they may be allergic to, so these can be strictly avoided in future. It is important to be aware that an allergy to one substance can lead to allergies to a number of related substances.

Populations with an increased risk of side effects from the use of adrenaline
You may have a greater risk of developing side effects with EURneffy if you:
- have cardiovascular disease (disease affecting the heart and blood circulation)
- have increased pressure in your eyes
- have reduced renal (kidney) function
- have prostatic adenoma (a benign (not cancer) condition in which an overgrowth of prostate tissue pushes against the urethra and the bladder, blocking the flow of urine)
- have hypercalcaemia (high blood calcium levels)
- have hypokalaemia (low blood potassium levels)
- have Parkinson’s disease
- have hyperthyroidism (an overactive thryoid gland)
- have hypertension (high blood pressure)
- have diabetes
- are elderly
- are pregnant (see section 2 Pregnancy, breast-feeding and fertility).

Talk to your doctor if any of the above conditions apply to you, or if you are not sure.

Children and adolescents
Do not give this medicine to children weighing less than 30 kg. The safety and efficacy of this medicinal product is unknown in children below 30 kg body weight.

Other medicines and EURneffy
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you take any of the following as they may reduce the effect of adrenaline:

- Alpha and Beta-blocking medicines, e.g. propanolol.
- Medicines that counteract the pressor effects of adrenaline (vasodilators or alpha-adrenergic-blocker, e.g. phentolamine).

You must also tell your doctor or pharmacist if you take any of the following as they may increase the risk of side effects of adrenaline:

- Medicines that may make the heart sensitive to arrhythmias (abnormal or irregular heartbeat), such as digoxin, mercurial diuretics (medicines that increase urine production which act mainly on the transport of sodium) (e.g. chlormerodrin, merbaphen, mersalyl acid, meralluride, mercaptomerin, mercurophylline, merethoxylline procaine) or quinidine.
- Antidepressants such as tricyclic antidepressants, e.g. imipramine, or monoamine oxidase inhibitors (MAO inhibitors) (e.g. isocarboxazid, phenelzine, selegiline, tranylcypromine).
- Medicines for the treatment of Parkinson's disease such as catechol-O-methyl transferase inhibitors (COMT inhibitors) (e.g. entacapone, tolcapone, carbidopa-levodopa-entacapone, opicapone) and levodopa.
- Medicines for thyroid disease such as levothyroxine.
- Medicines that make you breathe more easily; used for asthma (theophylline).
- Medicines used in labour (oxytocin).
- Medicines used to treat allergies such as diphenhydramine or chlorpheniramine (antihistamines).
- Medicines that act on the nervous system (parasympatholytics) (e.g. atropine, cyclopentolate, homatropine, hyoscine, tropicaminde).

Patients with diabetes should carefully monitor their glucose levels after they use EURneffy, as adrenaline can reduce the amount of insulin made by the body, thus increasing the blood glucose level.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is limited experience of the use of adrenaline during pregnancy. If you are pregnant, do not hesitate to use EURneffy in an emergency, since you and your baby's lives may be in danger. Discuss this with your doctor if you are pregnant.

It is expected that the amount of EURneffy that is passed through breast-feeding is very low. For the emergency treatment of anaphylaxis, EURneffy should be used in breast-feeding women in the same manner as for non-breast-feeding patients.

EURneffy with alcohol
Tell your doctor if you are drinking alcohol because this can increase the side effects of adrenaline.

Driving and using machines
The ability to drive and use machines is unlikely to be affected by this medicine. Do not drive if you are having an anaphylactic reaction.

EURneffy contains sodium metabisulphite and benzalkonium chloride
EURneffy contains sodium metabisulphite, which may cause severe allergic reactions (hypersensitivity) or breathing difficulty (bronchospasm).

This medicine contains 0.04 mg benzalkonium chloride in each dose. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used repeatedly.

3. How to use EURneffy

Always use EURneffy exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When to carry EURneffy
You should always carry EURneffy with you or have it close at all times in the event of an allergic emergency. Always carry at least two containers of EURneffy in the event a second dose is needed due to a mistake in taking the medicine or insufficient response after the first dose.

Always tell your friends and family that you carry EURneffy with you.

Dose
The recommended dose for patients with a body weight of 30 kg or more, is a single-dose of EURneffy nasal spray delivering 2 mg of adrenaline. The maximum dose of adrenaline for the emergency treatment of allergic reactions is 4 mg, taken as two separate single-dose nasal sprays.

Use in children
The recommended dose for patients with a body weight of 30 kg or more is a single nasal administration of 2 mg adrenaline. The maximum dose that may be given is 4 mg taken as two separate single-dose nasal sprays.

Method of administration
EURneffy must be given nasally (in the nose) only. EURneffy is a ready-to-use single-dose nasal spray that delivers its entire content (2 mg) upon activation. EURneffy can be used even if you have a cold or a congested nose.

Do not press the plunger before inserting the EURneffy nasal spray into a nostril, otherwise the single dose will be lost prior to use.

EURneffy should only be given as a nasal spray into a nostril; do not spray EURneffy into the eyes or mouth.

The instructions for use must be carefully followed in order to use EURneffy correctly.

If you notice the signs of an acute allergic reaction (see section 2 Warnings and precautions), use EURneffy immediately. Seek emergency medical assistance immediately to have close monitoring of the anaphylactic episode and in the event further treatment is required. Ideal dosing is to use the dominant hand to hold the sprayer and administer to the same side nostril (e.g., right hand to right nostril; or left hand to left nostril).

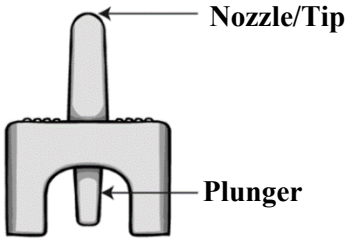
Sometimes a single dose of EURneffy may not be sufficient to completely reverse the effects of a serious allergic reaction. If your symptoms have not improved or have deteriorated within approximately 10 minutes after using the first nasal spray of EURneffy, either you or the person with you should give a second nasal spray of EURneffy in the same nostril as the first dose.

The instructions for use given below must be followed.

Instructions for use
Before you need to use it, fully familiarise yourself with EURneffy, including when and how it should be used.

EURneffy 2 mg nasal spray

EURneffy 2 mg nasal spray:



Follow these instructions only when ready to use.

A

Remove EURneffy 2 mg nasal spray from packaging.
Pull open the packaging to remove the EURneffy 2 mg nasal spray.

B

Hold the nasal spray as shown.
Hold the nasal spray with your thumb on the bottom of the plunger and one finger on either side of the nozzle.

- **Do not pull or push on the plunger**
- **Do not test or pre-spray; each nasal spray has only one dose.**

C

Insert tip of nasal spray into a nostril until your fingers touch your nose.

Keep the nozzle straight into the nose pointed toward your forehead. Do not angle the nasal spray to the inner or outer walls of the nose.

D

Press plunger up firmly until it snaps up and sprays into the nostril.

Do not angle the nasal spray to the inner or outer walls of the nose.

Seek immediate medical attention after use.
Seek emergency medical assistance immediately to have close monitoring of the anaphylactic episode and in the event further treatment is required.

Monitor patient symptoms

If symptoms continue to worsen or reoccur after approximately 10 minutes, or in any error of dosing, use a new EURneffy nasal spray, to give a 2nd dose in the SAME nostril as the first dose and seek urgent emergency medical assistance.

If necessary, you can lie down with feet raised. If this makes you breathless, you should sit up. Unconscious patients should be placed on their side in the recovery position to prevent choking. If symptoms do not resolve, you should, if possible, remain with another person until medical assistance arrives.

If you use more EURneffy than you should
In case of an overdose of the adrenaline, you should always seek **immediate** medical help. Overdose may cause a sudden increase in blood pressure (with symptoms including headache or dizziness), bleeding in brain tissue, palpitations (forceful heartbeats that may be rapid or irregular), reduced blood flow and accumulation of fluid in the lungs (causing symptoms including difficulty breathing). You will need to be monitored.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if any of the following side effects occur or worsen.

The following side effects are associated with the use of EURneffy nasal spray:

Very Common (may affect more than 1 in 10 people)

- Nasal discomfort
- Headache
- Feeling jittery

- Throat irritation

Common (may affect up to 1 in 10 people)

- Increased blood pressure
- Palpitations (forceful heartbeats that may be rapid or irregular)
- Rhinorrhea (runny nose)
- Anxiety
- Nasal oedema (itching and burning pain of the nose. Nose feels swollen, hot and red)
- Rhinalgia (nose pain)
- Heart rate increased
- Nasal congestion

Uncommon (may affect up to 1 in 100 people)

- Dizziness
- Lacrimation increased (watery eyes)
- Tremor (shaking)
- Oropharyngeal pain (pain in the tongue, soft palate, the side and back walls of the throat and tonsils).
- Nausea (feeling sick)
- Nasal pruritus (irritation or inflammation of the nose).
- Intranasal paraesthesia (sensations like numbness, tingling, pins and needles in the nose)
- Sneezing
- Paranasal sinus discomfort (nasal obstruction and congestion, nasal discharge that is thick, opaque, and coloured, and facial pain or pressure)
- Parasthesia oral (sensations like numbness, tingling, pins and needles in the mouth or back of the throat)
- Paraesthesia (sensations like numbness, tingling, pins and needles)
- Salivary hypersecretion (drooling)
- Toothache
- Head discomfort
- Nasal dryness
- Nasal mucosal disorder (inflammation of the tissue that lines the nasal cavity)
- Gingival discomfort (gum and mouth irritation)
- Energy increased
- Fatigue (feeling tired)
- Feeling hot
- Body temperature increased
- Presyncope (feeling faint)
- Euphoric mood
- Nervousness
- Pruritus (itching skin)
- Epistaxis (nosebleed)
- Chest discomfort

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store EURneffy

Keep this medicine out of sight and reach of children who are not the intended user.

Do not use this medicine after the expiry date which is stated on the nasal spray label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

If accidentally frozen, the nasal spray will not function. Allow the nasal spray to thaw for 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.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What EURneffy contains
- The active substance is adrenaline (epinephrine). Each dose of nasal spray solution delivers 2 mg adrenaline in 100 µL.
- The other ingredients are sodium chloride, dodecylmaltoside, disodium edetate, benzalkonium chloride, sodium metabisulphite (E 223), hydrochloric acid, concentrated (for pH-adjustment), sodium hydroxide (for pH-adjustment), water for injections (see Section 2. EURneffy contains sodium metabisulphite and benzalkonium chloride).

What EURneffy looks like and contents of the pack
The EURneffy 2 mg nasal spray, solution in single dose container is a non-pressurized dispenser delivering a single-dose spray containing the active substance in a clear and colourless to pink brownish solution.

EURneffy is available in packs containing 1 or 2 single dose nasal sprays.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
ARS Pharmaceuticals IRL, Limited
The Black Church
St Mary's Place
Dublin
D07 P4AX
Ireland

Manufacturer
Tiofarma B.V.
Hermanus Boerhaavestraat 1
3261 ME Oud-Beijerland
The Netherlands

This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site: https://www.ema.europa.eu.