

Introduction & How to Use

Please see full Important Safety Information throughout
and full Prescribing Information for *neffy* at neffyPRO.com

 **neffy**[®]
(epinephrine nasal spray)



Disclaimers



- The information being presented is consistent with the US FDA-approved label for **neffy** (epinephrine nasal spray), US FDA regulations and medical guidance
- ARS does not recommend the use of its product outside of the US FDA Label
- This slide deck is provided for educational and training purposes only



neffy Important Information (1/2)

INDICATION

neffy is indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 15 kg or greater.

IMPORTANT SAFETY INFORMATION

- It is recommended that patients are prescribed and have immediate access to two **neffy** nasal sprays at all times. In the absence of clinical improvement or if symptoms worsen after initial treatment, administer a second dose of **neffy** in the same nostril with a new nasal spray starting 5 minutes after the first dose.
- **neffy** is for use in the nose only.
- Advise patients when to seek emergency medical assistance for close monitoring of the anaphylactic episode and in the event further treatment is required.
- Absorption of **neffy** may be affected by underlying structural or anatomical nasal conditions.
- Administer with caution to patients who have heart disease; epinephrine may aggravate angina pectoris or produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or taking cardiac glycosides, diuretics, or anti-arrhythmics.
- The presence of a sulfite in **neffy** should not deter use.



neffy Important Information (2/2)

IMPORTANT SAFETY INFORMATION (Continued)

- **neffy** may alter nasal mucosa for up to 2 weeks after administration and increase systemic absorption of nasal products, including **neffy**.
- Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions.
- Epinephrine can temporarily exacerbate the underlying condition or increase symptoms in patients with the following: hyperthyroidism, Parkinson's disease, diabetes, renal impairment. Epinephrine should be administered with caution in patients with these conditions, including elderly patients and pregnant women.
- Most common adverse reactions are nasal discomfort, headache, rhinorrhea, dizziness, nausea, vomiting, throat irritation, nasal congestion, paresthesia, sneezing, upper respiratory tract congestion, epistaxis, rhinalgia, nasal dryness, dry throat, fatigue, and feeling jittery.
- These are not all of the possible side effects of **neffy**. To report suspected adverse reactions, contact ARS Pharmaceuticals Operations, Inc. at **1-877-MY-NEFFY (877-696-3339)** or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Epinephrine Treatment for Type 1 Allergic Reactions Including Anaphylaxis



Epinephrine is indicated as first-line treatment and is the only medication approved to **stop a potentially life-threatening allergic reaction**^{1,2}



Early recognition and use of epinephrine to treat symptoms and prevent progression to life-threatening respiratory and/or cardiovascular events¹



Reduce acute care activation and costs through prompt epinephrine usage for potential life-threatening reactions³



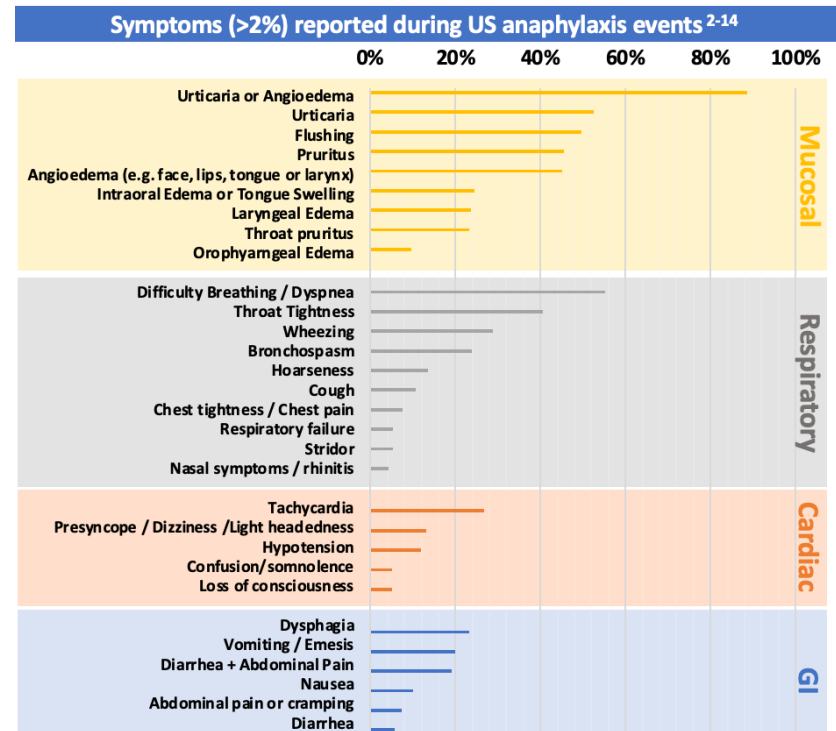
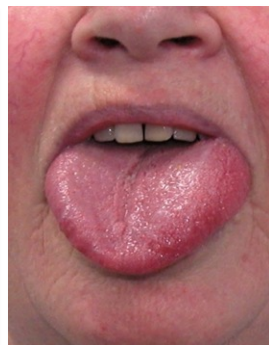
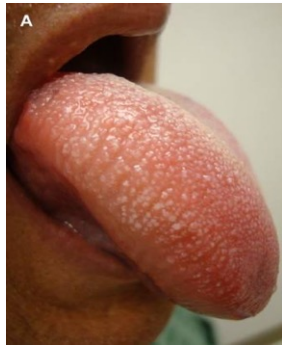
Anaphylaxis is Accompanied by Many Frequent Symptoms

Most Common Anaphylaxis Symptoms Include:

>85% urticaria (hives, erythema) or angioedema (swelling of the face, lips, tongue or larynx)

>55% difficult breathing

>40% gastrointestinal (e.g., vomiting, nausea)



Delays in Treatment with Epinephrine are Principally due to Needle-Injector Limitations and Accompanying Patient Reluctance



>40% of patients **do not fill or refill** their epinephrine prescription¹



55%-60% don't consistently **carry** epinephrine²⁻⁴

~40%
of patients
do not administer
epinephrine at all²

>50%
of parents
are afraid or somewhat
afraid to administer
their child's epinephrine⁵

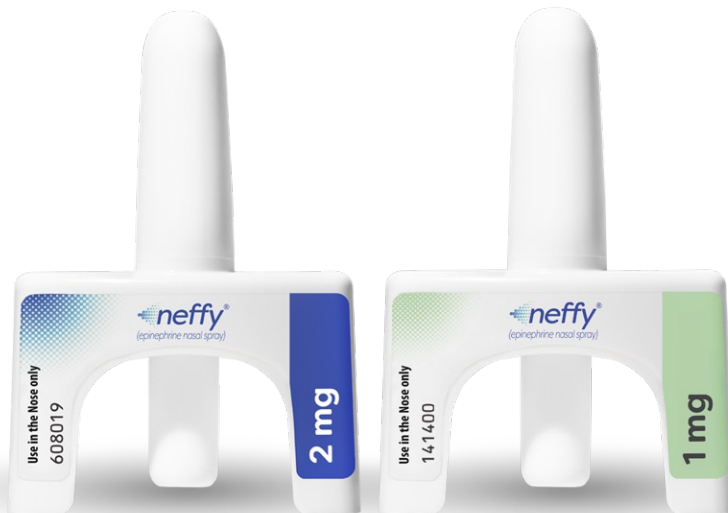
Without training

~70% don't administer
correctly⁶

With training

~20% don't administer
correctly⁷

Say hello to *neffy*: the same epinephrine found in a needle-injector, but in a nasal spray



2 mg approved by FDA:
August 9, 2024

1 mg approved by FDA:
March 5, 2025

- **neffy** is a compact, ready-to-use nasal spray indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 15 kg or greater.
- **neffy** is designed to be easy to use and easy to carry, so treatment is always close at hand.
- **neffy** is well tolerated and has no meaningful pain or irritation.
- **neffy** has some safety advantages over current epinephrine injection devices given the lack of a needle and need for injection. For example, the caregiver or medical professional cannot accidentally inject themselves in the hand or finger with neffy as often happens with injection products.



Safety and Tolerability

Table 2: Adverse Reactions with One or Two Dose(s) of Neffy with Incidence Greater than or Equal to 2% in Adults [Studies 1, 2, 3, and 4]

Adverse Reaction**	Neffy 2 mg One Dose	Neffy 2 mg Two Doses*
	N = 134***	N = 85***
Nasal discomfort	13 (10%)	11 (13%)
Headache	8 (6%)	15 (18%)
Rhinorrhea	4 (3%)	6 (7%)
Dizziness	4 (3%)	2 (2%)
Nausea	4 (3%)	2 (2%)
Vomiting	3 (2%)	2 (2%)
Throat irritation	2 (2%)	16 (19%)
Feeling jittery	1 (1%)	9 (11%)
Abdominal pain	1 (1%)	3 (4%)
Tremor	0 (0%)	7 (8%)
Nasal pruritus	0 (0%)	3 (4%)
Sneezing	0 (0%)	3 (4%)
Gingival pain	0 (0%)	3 (4%)
Hypoesthesia oral	0 (0%)	3 (4%)
Nasal Congestion	0 (0%)	2 (2%)

* Two nasal doses of neffy 2 mg were administered 10 minutes apart

** Data include subjects with nasal allergen challenge induced rhinitis

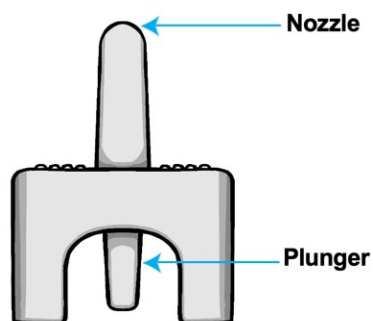
*** The trials used a crossover design and therefore the total number of subjects do not match the number of unique subjects (n = 175)

- Most common adverse events (>5%) following one dose were mild nasal discomfort (10%) and mild to moderate headache (6%)
- Adverse events generally mild in nature and resolve quickly
- No serious adverse events in any clinical studies
- No risk of needle-related injuries or blood vessel injections
- Pediatric subjects (n=21) who weigh 30 kg or greater received one nasal dose of **neffy** 2 mg and common adverse reactions reported in these subjects include nasal discomfort (19%), intranasal paresthesia (19%), rhinorrhea (19%), sneezing (14%), epistaxis (10%), rhinalgia (10%), paresthesia (10%), fatigue (10%), and feeling jittery (10%).
- Pediatric subjects (n=21) who weigh 15 to less than 30 kg received one nasal dose of **neffy** 1 mg and common adverse reactions reported in these subjects include nasal congestion (19%), upper respiratory tract congestion (14%), dry throat (10%), nasal dryness (10%), and paresthesia (10%).



Important Points about Use of *neffy*

Your *neffy* nasal spray device:



- *neffy* is for use in the nose only
- *neffy* nasal spray device is for allergic emergencies (anaphylaxis)
- Always carry two (2) *neffy* devices with you as a second dose may be needed (approximately 10% frequency with all epinephrine products)
- **Do not** test or prime (pre-spray) the device. Each *neffy* can only be sprayed 1 time and only had 1 dose
- Check your *neffy* periodically to be sure the expiration date has not passed and replace your *neffy* before expiration
- Get emergency medical help for further treatment of the anaphylactic emergency (anaphylaxis), if needed, after using *neffy*
- Emergency medical help may not be necessary if complete response after administration of *neffy*
 - Epinephrine is safe to use and is not the cause for emergency medical help. The reason for emergency help is to treat the allergic reaction if epinephrine is not completely effective after dosing.



How to use the *neffy* nasal spray device



Remove *neffy* from the packaging

- Pull open the packaging to remove the *neffy* nasal spray device from the packaging
- *neffy* nasal spray should be stored in its blister pack or in a *neffy* carrying case until ready to use
 - Beginning in Summer 2026, the *neffy* carrying case will be included in the carton containing *neffy*



How to use the *neffy* nasal spray device



Hold device as shown

- Hold the device with your thumb on the bottom of the plunger and a finger on either side of the nozzle
- Do not pull or push the plunger before activation
- Do not test or prime (pre-spray). Each device has only 1 spray (dose)



How to use the *neffy* nasal spray device

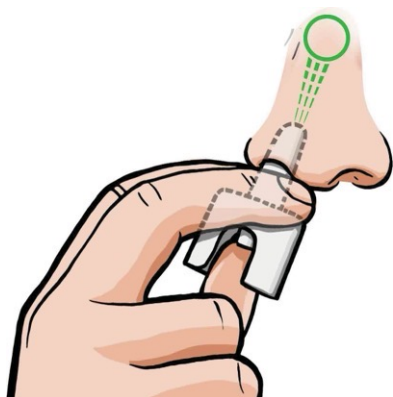


Insert the nozzle into a nostril until your fingers touch your nose, if possible

- Keep the nozzle straight into the nose pointed toward your forehead
- Do not point (angle) the nozzle to the nasal septum (wall between your 2 nostrils) or outer wall of the nose



How to use the *neffy* nasal spray device



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

- Avoid sniffing during or after receiving a dose of ***neffy***
- If you sniff by accident, monitor symptoms for at least 5 minutes and if they continue or get worse, give a second dose of ***neffy*** in the same nostril, if possible



For Caregiver Administration follow the same recommendations and dosing procedures, but from a caregiver perspective dosing a patient.

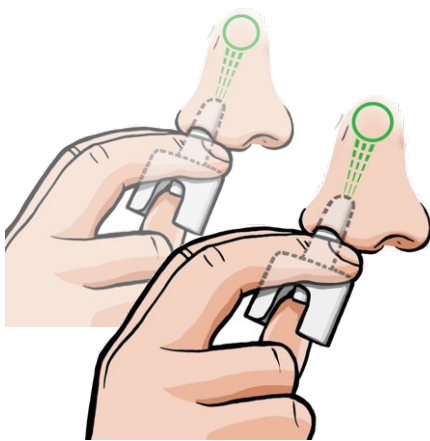


Get emergency medical help, if needed

- If needed after using **neffy**, get emergency help for further treatment of the allergic emergency (anaphylaxis). Tell them that a **neffy** nasal spray has been used
- Before you receive **neffy**, your healthcare provider should talk to you about when it is appropriate to get emergency medical help
 - For example: If after **neffy** is administered symptoms resolve and do not reoccur, emergency medical help may not be necessary
 - If a second dose of **neffy** is needed, give **neffy** first and then get additional emergency medical help to treat the anaphylaxis



When to give a second dose



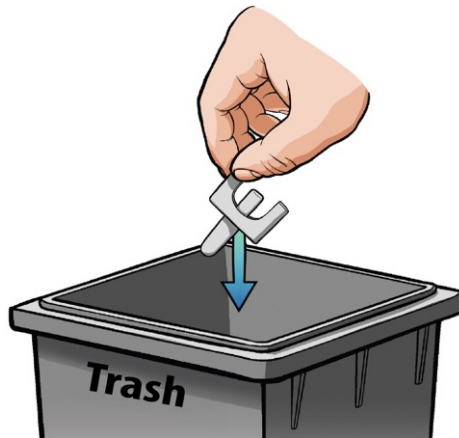
After 5 minutes, repeat dose if needed

- Check for symptoms after the first dose of **neffy**
- If symptoms get worse or come back, give a second dose of **neffy** in the **same nostril** starting at 5 minutes after the dose.

Note: an additional dose of **neffy** can be given at any time, if needed, after the first, but not before waiting at least 5 minutes to see if symptoms start to respond.



How to use the *neffy* nasal spray device



Throwing away the used *neffy* nasal spray device

- Throw away (dispose of) the used *neffy* nasal spray device in household trash
- Do not recycle

Storage and Handling of *neffy*



How should *neffy* be stored?

- Shelf life up to 2.5 years (2 mg) and 2 years (1 mg) from date of manufacture
- Store *neffy* at room temperature, between 68°F to 77°F (20°C to 25°C)
- Do not freeze. If *neffy* freezes, the device will not spray.
- *neffy* freezes below 5°F (-15°C). If *neffy* is accidentally frozen, the device will not spray, however *neffy* can be used if it has been thawed at room temperature for 20 minutes without damage to the device or the epinephrine
- *neffy* can be accidentally exposed to temperatures up to 122°F (50°C)



How-to-Use Videos



How-to-Use Video for *neffy* – Adolescent, Self-Administration





How-to-Use Videos for *neffy* – Caregiver Administration to Child



THANK YOU

For additional information and to order a *neffy* demo device visit www.neffypro.com

or contact

ARS Medical Information

Email: medinfo@ars-pharma.com

Phone: 877-MYNEFFY (877-696-3339) /Option 1



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