



**neffy**<sup>®</sup>  
(epinephrine nasal spray)



**neffy**<sup>®</sup> (epinephrine nasal spray) is the first and only FDA-approved needle-free epinephrine nasal spray used to treat allergic emergencies including anaphylaxis in adults and children aged 4 years and older who weigh 33 lbs. or more, and who are at risk for or have a history of serious allergic reactions.<sup>1</sup>

Type I allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine.<sup>2</sup>

### The Need for a Needle-Free Treatment Option

The primary reason people with serious allergies and caregivers delay or avoid administration of epinephrine is a fear of needles,<sup>3</sup> which may lead to delays in treatment.

- Prompt epinephrine treatment at the first sign of symptoms is critical to stop disease progression, but approximately 60% of people do not consistently carry their epinephrine devices, and most only carry one device when two are recommended.<sup>4</sup>
- While epinephrine auto-injectors have been shown to be effective, there are well published limitations that result in many people and caregivers delaying or not administering treatment in an emergency situation. These include:
  - needle-related injuries (e.g., injection into the thumb),<sup>6</sup>
  - size and temperature sensitive

There are approximately 40 million people in the U.S. who experience Type I allergic reactions primarily due to food, venom or insect stings. Of this group, six million are children with food allergies, with more than two million likely experiencing a severe reaction at some point.<sup>7</sup>

- Research shows that approximately 40% of people delay treatment,<sup>8</sup> and 56% of caregivers fear using needle-based auto-injectors on their child.<sup>5</sup> **neffy** eliminates needles, delivering a precise epinephrine dose via a simple nasal spray, almost instantly, with no nasal hold time required.

### Attributes of neffy



Needle-free administration



Proven device used by current FDA-approved emergency therapies



Pocket-sized device



No risk of needle-related injuries

**neffy** uses Intravail<sup>®</sup> technology, which temporarily loosens the spaces between the nasal cells to help epinephrine be absorbed into the body.<sup>9</sup> **neffy** can be used with a stuffy nose.<sup>1</sup>

## Clinical Attributes

**neffy** delivers the same epinephrine as an auto-injector but in a nasal spray. The epinephrine in **neffy** is designed to be rapidly absorbed into the nasal passage to reverse the allergic reaction, including anaphylaxis. Clinical highlights include:

- **neffy** demonstrated response on systolic blood pressure within one minute of dosing.<sup>10</sup>
- **neffy** was shown to result in pharmacokinetic and pharmacodynamic responses that were comparable or higher than intramuscular epinephrine administered by healthcare providers.<sup>11</sup>
- In a study of 90 patients, 100% correctly self-administered **neffy** to themselves or someone else.<sup>12</sup> Human factor studies also showed children as young as 10 years old can use **neffy** effectively by following instructions, and that even untrained individuals, such as babysitters or teachers, can effectively administer **neffy**.<sup>12</sup>
- Clinical evaluation suggested that upper respiratory tract infections, allergic rhinitis and infectious rhinitis do not affect epinephrine exposure or maximum absorption after administration of **neffy**.<sup>13</sup>
- The most common side effects of **neffy** include nasal discomfort, headache, throat irritation, chest and nasal congestion, feeling overly excited, nervous or anxious, nose bleed, nose pain, sneezing, runny nose, dry nose or throat, tingling sensation, including in the nose, feeling tired, dizziness, nausea, and vomiting.<sup>1</sup>
- The shelf life for **neffy** 1 mg is 24 months and the shelf life for **neffy** 2 mg is 30 months.<sup>10</sup> **neffy** can be stored at room temperature between 68° and 77° F<sup>1</sup> and at high temperatures up to 122° F for a few days.<sup>1</sup> Do not freeze **neffy**, as if freezes **neffy** will not spray.<sup>1</sup>

## INDICATION AND IMPORTANT SAFETY INFORMATION FOR **neffy**<sup>®</sup> (epinephrine nasal spray)

### WHAT IS **neffy**?

**neffy** is a nasal spray used for emergency treatment of allergic reactions including anaphylaxis, in adults and children aged 4 years and older who weigh 33 lbs or greater.

### IMPORTANT SAFETY INFORMATION

#### What is the most important information that I should know about **neffy**?

**neffy** contains epinephrine, a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life-threatening,



***neffy** is easy-to-use.  
The device is small,  
making it convenient to carry.*

The logo for neffyconnect, featuring a stylized grid icon to the left of the text "neffyconnect" in a lowercase, sans-serif font.

To help ensure affordability and access, the **neffyConnect** program provides patients, caregivers and healthcare professionals with information about patient support programs, such as medication fulfillment services and financial support for eligible patients to help guide their treatment journey, including navigating insurance requirements and potential barriers to access. **neffyConnect** will also provide families with helpful educational resources and tools.

**For more information and to enroll, please visit [neffy.com](https://neffy.com) or call 1-877-myneffy (1-877-696-3339).**

can happen in minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or other unknown causes.

Always carry two **neffy** nasal sprays with you because you may not know when anaphylaxis may happen and because you may need a second dose of **neffy** if symptoms continue or come back. Each **neffy** contains a single dose of epinephrine. **neffy** is for use in the nose only.

Use **neffy** right away, as soon as you notice symptoms of an allergic reaction. If symptoms continue or get worse after the first dose of **neffy**, a second dose is needed. If needed, administer a second dose using a new **neffy** in the same nostril *starting 5 minutes after the first dose*. Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed after using **neffy**.

Tell your healthcare provider if you have underlying structural or anatomical nasal conditions, about all the medicines you take, and about all your medical conditions, especially if you have heart problems, kidney problems, low potassium in your blood, Parkinson's disease, thyroid problems, high blood pressure, diabetes, are pregnant or plan to become pregnant, or plan to breastfeed.

Tell your healthcare provider if you take or use other nasal sprays or water pills (diuretics) or if you take medicines to treat depression, abnormal heart beats, Parkinson's disease, heart disease, thyroid disease, medicines used in labor, and medicines to treat allergies. **neffy** and other medications may affect each other, causing side effects. **neffy** may affect the way other medicines work, and other medicines may affect how **neffy** works.

## What are the side effects of **neffy**?

**neffy** may cause serious side effects. If you have certain medical conditions or take certain medicines, your condition may get worse, or you may have more or longer lasting side effects when you use **neffy**.

Common side effects of **neffy** include: nasal discomfort, headache, throat irritation, chest and nasal congestion, feeling overly excited, nervous or anxious, nose bleed, nose pain, sneezing, runny nose, dry nose or throat, tingling sensation, including in the nose, feeling tired, dizziness, nausea, and vomiting.

**Tell your healthcare provider if you have any side effects that bother you or that do not go away after using **neffy**.**

These are not all of the possible side effects of **neffy**. Call your healthcare provider for medical advice about side effects. To report side effects, contact ARS Pharmaceuticals Operations, Inc. at **1-877-MY-NEFFY (877-696-3339)** or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Please see the full [Prescribing Information](#) and [Patient Information](#) for **neffy**.**

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1. neffy Epinephrine Nasal Spray Full Prescribing Information. ARS Pharma. 3-2025. 2. Quoc QL et al. Recent update on the management of anaphylaxis. Clin Exp EmergMed 2021;8(3):160-172. <https://doi.org/10.15441/ceem.21.12>. 3. Kaplan H et al. Epinephrine auto-injector prescriptions are not filled due to dislike of needles: results of a patient survey. Presented at: American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting; February 24, 2023; San Antonio, TX. 4. Warren CM, Zaslavsky JM, Kan K, Spergel JM, Gupta RS. Epinephrine auto-injector carriage and use practices among US children, adolescents, and adults. Ann Allergy Asthma Immunol. 2018 Oct;121(4):479-489.e2. doi: 10.1016/j.anai.2018.06.010. Epub 2018 Jun 21. PMID: 29936229. 5. Chad L et al. A majority of parents of children with peanut allergy fear using the epinephrine auto-injector. Allergy. 2013;68(12):1605-1609. <https://doi.org/10.1111/all.12262>. 6. Fitzcharles-Bowe C et al. Finger injection with high-dose (1:1,000) epinephrine: Does it cause finger necrosis and should it be treated? Hand (N Y). 2007 Mar;2(1):5-11. doi: 10.1007/s11552-006-9012-4. 7. Food Allergy Research & Education. Facts and Statistics. Available at Facts and Statistics - FoodAllergy.org. Accessed January 24, 2025. 8. Sheikh A, Dhimi S, Regent L, Austin M, Sheikh A. Anaphylaxis in the community: a questionnaire survey of members of the UK Anaphylaxis Campaign. JRSM Open. 2015 Jul28;6(7):2054270415593443. doi: 10.1177/2054270415593443. 9. Neurelis Press Release. Neurelis Announces that Intravail® License, ARS Pharmaceuticals' Intranasal Epinephrine Product, Demonstrates Bioequivalent Exposure to Epinephrine Injectors. May 4, 2020. 10. ARS Pharma Data on File. 11. Casale TB et al. Pharmacokinetics of Self-Administration of ARS-1 (neffy® Nasal Spray) 2.0 mg Versus Manual Intramuscular (IM) Epinephrine 0.3 mg by Health Care Provider (HCP). Presented at: American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting; February 24, 2023; San Antonio, TX. 12. Lowenthal R et al. Self-Administration of Intranasal Epinephrine (neffy) Using the Aptar Unit Dose System Compared to EpiPen and Symjepi. Presented at the Annual Meeting of the American Academy of Allergy, Asthma and Immunology; February 25-28, 2022; Phoenix, AZ. 13. Oppenheimer J et al. Pharmacokinetics/Pharmacodynamics of Intranasal Epinephrine in Subjects with and without Upper Respiratory Infections Presented at the American College of Allergy, Asthma and Immunology (ACAAI); November 9-13, 2023; Anaheim, CA.