

neffy®

(epinephrine nasal spray) 2 mg

neffy® (epinephrine nasal spray) is the first and only FDA-approved needle-free epinephrine medicine for the emergency treatment of Type I allergic reactions, including anaphylaxis, in adults and children who weigh 30 kg (66 lbs.) or more.¹

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.²

neffy demonstrated rapid, reliable delivery of epinephrine levels comparable to currently approved injectable products.³



The Need for a New Treatment Option

The primary reason people with severe allergies and caregivers delay or avoid administration of epinephrine is the fear of the needle-injector,⁴ which may lead to delays in treatment.

- Prompt epinephrine treatment at the first sign of symptoms is critical to stop disease progression.⁵
- For decades, the only way to administer epinephrine has been through needle-based products that:
 - Can carry risks such as needle-related injuries (e.g., injection into the thumb),⁶
 - May be inconvenient to carry and temperature sensitive,
 - Can be difficult or anxiety-provoking to use for people with life-threatening allergies, as well as their caregivers, such as parents or teachers.⁷

There are approximately 40 million people in the U.S. who experience Type I allergic reactions primarily due to food, venom or insect stings.⁸

- Only about half (~20 million) are under a physician's care, with only about three million having a current prescription for epinephrine, of which 80–90% do not carry or administer as indicated in a timely manner.⁸

Attributes of neffy



Needle-free administration



Proven device used by current emergency therapies



Pocket-sized device



No risk of needle-related injuries

neffy is the first and only epinephrine nasal delivery method approved.¹ It is the same proven device used for emergency treatment such as with NARCAN® Nasal Spray.⁹

Please see Important Safety Information on page 3.

Clinical Attributes

In clinical studies, **neffy** has been tested in more than 700 adults and children³ and has shown to be safe and well-tolerated.³ **neffy** is a needle-free, pocket-sized, easy-to-use nasal spray.

Clinical highlights include:

- **neffy** demonstrated response on systolic blood pressure within one minute of dosing.³
- Self-administration of **neffy** was shown to result in pharmacokinetic and pharmacodynamic responses that were comparable or higher than intramuscular epinephrine administered by healthcare providers.¹⁰
- In a study of 90 patients, 100% correctly self-administered **neffy** to themselves or someone else.¹¹
- 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**.¹²
- The most common adverse reactions may include throat irritation, tingling nose, headache, nasal discomfort, feeling over excitement, nervousness or anxiety, tingling sensation, fatigue, shakiness, runny nose, itchy nose, sneezing, stomach pain, pain in gums or teeth, numbness in the mouth, nasal congestion, dizziness, nausea, and vomiting.¹
- **neffy's** shelf-life is 30 months³ and was shown to be stable at temperatures up to 122 F for months or after thawing if accidentally frozen.¹

Please see Important Safety Information on page 3.

1. neffy Epinephrine Nasal Spray Full Prescribing Information. ARS Pharma. 06-2024. 2. Quoc QL et al. Recent update on the management of anaphylaxis. Clin Exp Emerg Med 2021;8(3):160-172. <https://doi.org/10.15441/ceem.21.12>. 3. ARS Pharma Data on File. 4. 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. 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. Asthma and Allergy Foundation of America. My life with food allergy: parent survey report. Published 2019. 8. Data Derived from IQVIA Claims Data, 2023. 9. NARCAN Nasal Spray. Full Prescribing Information. Adapt Pharma. 8/20. 10. 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. 11. 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. 12. 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.



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



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 or
call 1-877-myneffy
(1-877-696-3339).**



INDICATION AND IMPORTANT SAFETY INFORMATION FOR *neffy*[®] (epinephrine nasal spray)

What is *neffy*?

neffy 2 mg is a nasal spray used to treat life-threatening, allergic emergencies including anaphylaxis, in adults and children who weigh 66 lbs or more (30 kg or more), who are at risk for or have a history of serious allergic emergencies.

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, 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. *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, 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*.**

Side effects of *neffy* may include throat irritation, tingling nose, headache, nasal discomfort, feeling over excitement, nervousness or anxiety, tingling sensation, fatigue, shakiness, runny nose, itchy nose, sneezing, stomach pain, pain in gums of teeth, numbness in the mouth, nasal congestion, 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.

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Please see accompanying full prescribing information.