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IN BRIEF

Epinephrine 1 mg Nasal Spray (*neffy*)

The FDA has approved a 1-mg epinephrine nasal spray (*neffy* - ARS Pharma) for emergency treatment of type 1 hypersensitivity reactions including anaphylaxis in patients ≥ 4 years old who weigh 15 to < 30 kg. A 2-mg formulation of *neffy* was approved in 2024 for use in patients who weigh ≥ 30 kg.¹

CLINICAL STUDIES – FDA approval of the 1-mg formulation of *neffy* was based on the results of a pharmacologic study (summarized in the package insert) that included 21 children ≥ 4 years old who weighed 15 to < 30 kg. Geometric mean plasma epinephrine concentrations in the children after a 1-mg dose were higher than those in a reference group of adults after a 2-mg dose.

ADVERSE EFFECTS – Adverse effects of the 1-mg dose included nasal and upper respiratory tract congestion, dry throat, nasal dryness, and paresthesia. The nasal spray solution contains sodium metabisulfite, which could cause a hypersensitivity reaction in patients with a sulfite allergy, but a history of sulfite sensitivity should not deter emergency use of the product.

DOSAGE, ADMINISTRATION, AND COST – The recommended dosage of *neffy* in children ≥ 4 years old who weigh 15 to < 30 kg is one 1-mg spray administered into one nostril. If symptoms have not improved after 5 minutes, a second spray can be administered into the same nostril using a new device. The nasal spray should be stored at room temperature, but excursions up to 50° C (122° F) are permitted. At temperatures below -15° C (5° F), the solution freezes and the device cannot deliver epinephrine. The shelf life of *neffy* 1 mg is 24 months (the 2-mg formulation has a shelf life of 30 months).

Table 1. Some Epinephrine Products for Anaphylaxis in Patients Weighing 15 to < 30 kg

Product	Usual Dosage ¹	Cost ²
Auto-Injectors		
<i>EpiPen Jr</i> (Mylan)	0.15 mg IM or SC	\$608.60 ⁴
generic (Mylan, ³ Teva)		300.00 ⁴
generic (Amneal) ⁵	0.15 mg IM or SC	300.00 ⁶
<i>AUVI-Q</i> (Kaléo) ⁷	0.15 mg IM or SC	621.90 ⁸
Nasal Spray		
<i>neffy</i> (ARS Pharma) ⁹	1 mg intranasally	710.00 ¹⁰

1. A second dose can be administered using a new device if needed.
2. Approximate WAC for two doses. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly, April 5, 2025. Reprinted with permission by First Databank, Inc. All rights reserved. ©2025. www.fdbhealth.com/policies/drug-pricing-policy.
3. The Mylan product is an authorized generic drug.
4. Mylan provides free epinephrine auto-injectors to eligible uninsured or underinsured patients who are from families earning less than 400% of the federal poverty level (<https://aspe.hhs.gov/poverty-guidelines>). Manufacturer-issued coupons for *EpiPen Jr* and its authorized generic are available for patients with commercial insurance.
5. Authorized generic of *Adrenaclick*, which has been discontinued.
6. Available at discounted prices at some pharmacies (at CVS pharmacies, the cash price is \$110.00 for a package containing two auto-injectors).
7. A 0.1-mg auto-injector formulation of *AUVI-Q* is available for use in patients weighing 7.5 to < 15 kg.
8. Kaléo provides free *AUVI-Q* auto-injectors to eligible uninsured patients who are from families earning less than 250% of the federal poverty level (<https://aspe.hhs.gov/poverty-guidelines>). According to the manufacturer, the out-of-pocket cost should not exceed \$35 for most patients with standard commercial insurance or \$199 for patients with high-deductible commercial insurance.
9. Approved for use in patients ≥ 4 years old.
10. According to the manufacturer, the out-of-pocket cost should not exceed \$25 for most patients with commercial insurance or \$199 for those using coupons from discount sites such as GoodRx.

The 1-mg formulation of *neffy* is expected to be available in May 2025. According to the manufacturer, the out-of-pocket cost for two *neffy* nasal spray devices should not exceed \$25 for most patients with commercial insurance.² ■

1. An epinephrine nasal spray (*neffy*) for anaphylaxis. *Med Lett Drugs Ther* 2024; 66:163.
2. ARS Pharma Press Release. ARS Pharmaceuticals announces FDA approval of *neffy* 1 mg (epinephrine nasal spray) for type I allergic reactions, including anaphylaxis, in pediatric patients weighing 15 to < 30 kilograms. March 5, 2025. Available at: <https://bit.ly/4kLwQ5a>. Accessed April 10, 2025.

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