

# Could a nasal spray replace an EpiPen? Here's what an allergist says

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For the millions of Americans who have a food allergy, doctors recommend they always carry an epinephrine auto-injector, such as an EpiPen, in case they have a severe allergic reaction. But a recently approved nasal spray may offer a needle-free alternative in the near future.



This August, the <u>U.S. Food and Drug Administration approved Neffy</u>, which is the first epinephrine product for the treatment of anaphylaxis that is not administered by injecting a needle.

Anaphylaxis is a severe and potentially life-threatening allergic reaction that can happen seconds or minutes after a person is exposed to something they are allergic to, such as certain foods, medications, or insect stings. Epinephrine is a medication used to treat anaphylaxis, and it traditionally is administered with an auto-injector—a needle—in the thigh.

Neffy is expected to be available in the U.S. by early October. Although it is not yet available to prescribe to patients in Colorado, Suzanne Ngo, MD, an allergist and immunologist at Children's Hospital Colorado and the UCHealth Allergy and Immunology Clinic, is brainstorming how to talk about the new product with her patients.

"It's very encouraging that there is this additional option because there has been a barrier of this medicine being administered with a shot. I think that can scare people from using it," says Ngo, an assistant professor in the Division of Allergy and Clinical Immunology at the University of Colorado Department of Medicine. "If we have other options that are just as effective, maybe there will be less hesitation to use it."

However, Ngo cautions that the efficacy of the device is still not fully known.

"We need time to know if it truly is equivalent to the EpiPen because, as of right now, most of the studies have been primarily on healthy people," she says. "There's been more limited data on actually using it in the setting of an allergic or an <u>anaphylactic reaction</u>, so I think that's where being able to collect more of that data will give us more confidence with



using it."

#### How it works

Neffy can be used on both adults and children who weigh more than 66 pounds. It is a single-dose <u>nasal spray</u> that is administered into one nostril.

"It essentially has epinephrine in it, which then is absorbed into the <u>nasal</u> <u>mucosa</u> and exerts its effects. There are other medications that have utilized the same sort of nasal delivery approach, such as Narcan, which is used in <u>emergency situations</u> for opioid overdoses," Ngo says.

On its <u>website</u>, Neffy recommends carrying two Neffy devices at all times. A second dose can be given if there is no improvement in symptoms or if symptoms worsen. This second dose involves using a new nasal spray to administer Neffy in the same nostril.

Neffy advises users to not sniff during or after use. It also recommends that if a person is using their right hand to administer the medicine, the spray should go in the right nostril; similarly, left-handed dosing should be to the left nostril.

"The hope is that those who are more hesitant to use a needle may be more willing to use this to treat a severe allergic reaction," Ngo says. "It's also a slightly smaller device that may be easier to carry than an auto-injector."

## **Potential concerns**

Given that it is a nasal spray, there have been some concerns about whether Neffy can get the medicine into a person's system as effectively



as an auto-injector can.

"One potential concern was that a lot of our patients have nasal allergies and always have a runny nose. And if you have a child who is having an allergic reaction and crying and snotty, are we able to get enough medication in their system?" Ngo says.

"But they have done studies where they tested patients who have nasal allergies, where they essentially exposed them to things they're allergic to in order to set off those nasal symptoms and then used Neffy.

"Those preliminary studies indicated that it didn't affect the absorption of the medication. If that is consistent when treating <u>allergic reactions</u>, I think that's reassuring because that's one of the concerns many people will have," she adds.

Another concern Ngo has about Neffy is the ability to quickly administer the medicine to a child who is not cooperating.

"It's a bit easier to hold a child's leg still and do an injection versus administering the nasal spray for a child who may be moving their head around," she says. "The worry is, if you aren't able to spray it where it needs to go, you may be losing that medication and not treating the child."

Cost is also a potential concern, Ngo says, because it is unknown how different insurance policies may cover Neffy.

"That's always something we have to consider, because there are different epinephrine devices out there and we sometimes have to pick whichever product the patient's insurance will cover. That may differ from patient to patient," she says.



### The need for more data

Ngo wants patients to keep in mind that most of the studies on Neffy have primarily been on healthy people who were not experiencing anaphylaxis—a limitation of the clinical trials due to ethical guidelines.

"Because this is potentially a life-threatening reaction that we're treating, the ethics of inducing anaphylaxis to someone just to test Neffy's efficacy is not feasible," she says. "However, we have other opportunities when patients are more likely to have anaphylaxis, such as a food challenge procedure, where we can study effectiveness for Neffy to treat anaphylaxis."

As Neffy becomes more available and is used to treat people experiencing anaphylaxis in real-life scenarios, it will be important to collect data on the efficacy of the device. This data can then help allergists like Ngo decide whether they want to advise their patients to use the product or not.

"I think we're all cautiously preparing for how we are going to recommend this to patients until we gather a bit more data to reassure us that this is going to be just as effective in treating those reactions as an auto-injector is," she says.

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