

# US FDA approves first nasal spray to treat severe allergies: Here's how it can change treatment

Called Neffy, it is an alternative to injections and can manage an emergency better.

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The United States Food and Drug Administration (FDA) recently approved the first-ever nasal spray for treating anaphylaxis, a severe and life-threatening allergic reaction that demands immediate medical attention and an injection of epinephrine, a hormone shot that fights the allergen.

So now you can replace these shots and treat the condition painlessly and conveniently with the new epinephrine nasal spray called Neffy, developed by the US-based ARS Pharmaceuticals. It has been designed for the [emergency treatment of Type I allergic reactions](#), including those that are life-threatening and are caused by food, medication and insect bites. This approval applies to both adults and children who weigh at least 30 kg. The US FDA has approved the 2 mg version for treatment.

## What is epinephrine?

This is a hormone medication that relaxes the muscles in the airways and constricts the blood vessels, making it the only life-saving treatment for anaphylaxis. As an injection, it is administered alongside emergency medical care to treat life-threatening allergic reactions triggered by insect bites or stings, foods, medication, latex or other causes.

## Why is the US FDA approval significant?

Dr Pravin Hissaria, Head of Clinical Immunology and Allergy at Royal Adelaide Hospital, Australia, and a consultant at Zydus Hospital in [Ahmedabad](#), says Neffy could be transformative in low- and middle-income countries which lack auto-injectors, compelling patients to manually draw and administer adrenaline. "Epinephrine auto-injectors must be kept at a specific temperature and carried in an ice pack because severe allergic reactions can occur anytime. However, in places like India, where we need to teach patients how to draw the correct amount of adrenaline and inject it themselves — a time-consuming process — a nasal spray could be a game changer," says Dr Hissaria.

Allergy consultant Dr Raj Bhagat says a spray could benefit children the most. "They fear injections and they cannot manually draw and inject adrenaline on their own. Parents also worry about leaving these children unsupervised because they might develop anaphylaxis and need precise dosing. An easy-to-use nasal spray could resolve the issue," he says.

## What's the efficacy of Neffy?

Neffy's FDA approval was based on four studies conducted with 175 healthy adults who did not have anaphylaxis. These compared the levels of epinephrine in the blood of subjects after using Neffy with those who used the traditional epinephrine injections. Neffy delivered similar levels of epinephrine in the blood as the approved injection products. Additionally, Neffy had similar effects on increasing blood pressure and heart rate, which are critical in treating anaphylaxis.

## What is the incidence of severe allergic reactions reported in India?

Dr Hissaria points out that the incidence of anaphylaxis in India is under-reported, largely because the field is spread across various medical specialities and there haven't been enough studies in the country. "While

anaphylaxis caused by venom and medicines is well-known, food-induced anaphylaxis is becoming more common in India, possibly due to globalisation and changing lifestyles. So a nasal spray shows great promise,” he adds.

The three most common allergens are foods such as nuts, milk, fish, and certain fruits; medications including vaccines, anti-inflammatories, antibiotics and insect venom, particularly from wasps and bee stings. Foods affect children more, drugs affect more adults.

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