Phenylephrine = Placebo? What the FDA's recent ruling suggests

Sudafed has been a household name for decades, with the drug's active ingredient pseudoephedrine being around since the 1920s.

Recently, the U.S. Food and Drug Administration (FDA) claimed Sudafed PE, one of Sudafed's more popular items, is not effective and should be banned from over-the-counter use. The announcement came roughly a year after a panel of advisors to the FDA unanimously said phenylephrine doesn't work to clear up congestion when taken orally.

The PE in Sudafed PE comes from another active ingredient, phenylephrine, marketed as a product taken by mouth that *should* provide temporary relief of nasal congestion. Many other over-the-counter (OTC) combination drugs contain phenylephrine, including some items under the brand names NyQuil, Benadryl and Mucinex.

The FDA advisor panel's decision led CVS pharmacy to pull common cold and cough medicines from store shelves in October 2023, which list phenylephrine as the main ingredient.

"It is the FDA's role to ensure that drugs are safe and effective," said Patrizia Cavazzoni, MD, director of the FDA's Center for Drug Evaluation and Research (CDER). "Based on our review of available data, and consistent with the advice of the advisory committee, we are taking this next step in the process to propose removing oral phenylephrine because it is not effective as a nasal decongestant."

The FDA points out that while phenylephrine is found in many nasal sprays as well, its recommendation is only related to orally administered phenylephrine.

Entering public comment period

Jason Scheid, the director of Pharmacy Services for Community & Specialty Pharmacy for OSF HealthCare, says the FDA is now seeking public comments on its proposal until May 7, 2025. A final order will be issued after the 180-day comment period.

"At that point (after the 180 days) the FDA will provide the manufacturers with their due warning whether they have to pull the products or reformulate it to find an alternative that meets the labeling requirements," Scheid says.

Scheid anticipates if drugmakers wanted to reformulate these products, and wanted them to remain as oral decongestants, the companies would have to put pseudoephedrine into the products. This would push more products behind the pharmacy counter, like the original Sudafed.

"If you're looking for an oral decongestant, the original Sudafed is a good alternative," Scheid adds. "You have to show your ID and there are purchase limitations. It has shown itself to be an effective alternative. There are nasal decongestants you can try, like Afrin. There's also nasal steroids and antihistamines, this gets more into the allergy nasal sprays that can help prevent congestion symptoms. You can pick any of those up over the counter at a local pharmacy."

Phenylephrine or Placebo?

The FDA clarifies that while it's proposing these products be banned from store shelves, there aren't any safety concerns attached to them. They're simply just not effective. Many medications will claim to offer multiple benefits. For example, Mucinex Sinus-Max® claims to clear sinus congestion and relieve headaches, while thinning and loosening mucus. But the drug also has Acetaminophen and Guaifenesin in it. Scheid says this proposal simply targets the phenylephrine component when considering nasal decongestion, so other benefits might still be possible.

“It might provide you a placebo-type effect. You might just feel better because of the other ingredients in it, but that one (phenylephrine) solely is not meeting the effectiveness criteria to remain over the counter,” Scheid says.

Natural treatment options that can relieve symptoms

“Using that hot shower or cool mist humidifier will add moisture to where you are to help with that congestion,” Scheid says. “Something as simple as saline nasal spray will add some moisture to the nasal cavity and give some relief.”

It’s always important to clean your humidifier after each use to prevent mold and other bacteria from being released in the air.

Don’t overdo it on the nasal sprays

Another reason why it’s important to read labels is the effect nasal sprays can have if they are used longer than their intended use. Most nasal decongestant sprays will recommend using the product for three days or less.

“What happens is a rebound nasal congestion, where you lose the effectiveness of the medication to relieve that pressure, and it causes more pressure if it’s used more than just a couple days,” Scheid says.

If congestion is caused by allergies

About one quarter (25.7%) of American adults have a seasonal allergy, according to the Centers for Disease Control and Prevention (CDC), while nearly one in five (18.9%) children are affected. Scheid says treating nasal congestion for those with allergies is a longer-lasting issue.

“You’re looking at longer-term solutions then. You’re either using a long-term nasal steroid spray or antihistamine spray, or oral antihistamine.”

Scheid says if the FDA’s proposal goes through in May, pharmacy shelves will look a whole lot different than they do now.

Another way to clear congestion is to stay hydrated. Drinking water will help thin out mucus discharge from the nose and loosen up any phlegm in the lungs, making it easier to cough up.