

Why popular nasal decongestants with phenylephrine (like Sudafed PE) don't work, and what does

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If you've ever trekked to your local pharmacy to treat a stuffy nose, it's likely you were disturbed by an FDA panel's conclusion that a key



ingredient in over-the-counter oral cold medications works no better than a placebo.

The government advisers voted unanimously Tuesday against the effectiveness of phenylephrine, the key ingredient in Sudafed PE, Vicks Nyquil Severe, Vicks Sinex Severe and other popular cold medicines.

Mansoor Amiji, Northeastern distinguished professor in the School of Pharmacy and Pharmaceutical Sciences, talked to Northeastern Global News about what medications to use instead.

He also explained how the ineffective decongestants remained on the shelves for so long.

Why the decongestant doesn't work

Scientists advising the FDA recently found that in phenylephrine products taken orally—in a tablet or capsule—levels of the drug were "very very low" by the time it reached the nose, Amiji says.

"These drugs have to go into the stomach, then the intestine and the liver, before they get into the bloodstream and up to the nose where they are supposed to give relief from congestion," he says.

"What they found was that the blood levels of these drugs were not sufficient to actually reach all the way to the nose. That's why the FDA panelists say that they are not really providing any therapeutic benefit."

The solution is not to give phenylephrine orally at <u>higher doses</u> because it can cause <u>blood pressure</u> to soar too high, according to <u>an Associated Press article</u>.



Try a nasal spray instead

"However, if you take that drug and spray it in the nose, you do get a decongestant effect," Amiji says.

"Taken as a spray, phenylephrine basically constricts the blood vessel, decreasing swelling. That suddenly opens up the <u>nasal cavity</u> and allows us to breathe better."

In addition, he says, with nasal delivery, "You are limiting the systemic toxicity or side effects of this drug because the drug is locally delivered in the nose and doesn't go into the bloodstream and deliver all over the body."

Phenylephrine is so ineffective as an oral medication that even a simple saline <u>nasal spray</u> works better to relieve stuffiness, Amiji says.

"Really look into nasal sprays and other options that treat conditions in the <u>nose</u> directly."

Go to the pharmacy counter

"It's important to clarify that not all nasal decongestants are ineffective. It's only the ones that contain phenylephrine," Amiji says.

"Sudafed which is kept behind the (pharmacy) counter contains a different kind of decongestant called pseudoephedrine, and pseudoephedrine is effective" in relieving congestion, he says.

While phenylephrine is available over-the-counter on store shelves, pseudoephedrine has been kept behind pharmacy counters since 2006, courtesy of a law intended to stop it from being illegally processed into



methamphetamine.

While pseudoephedrine doesn't require a prescription, taking the extra step of requesting the medication from the pharmacist has led many a time-pressed person to grab a phenylephrine version, sometimes labeled PE on the package, on the way up to the cash register.

How has it remained on the shelves all these years?

The new research could result in phenylephrine eventually being pulled off the market.

But many question how an ineffective medication could remain in circulation for many years. The AP says versions of the <u>drug</u> have been "sold in various forms for more than 75 years."

While modern studies are showing it is no more effective than a dummy pill, phenylephrine's longevity and safety record protected it from scrutiny, Amiji says.

"I think there are many over-the-counter products that have historically been approved and continue to at least have a margin of safety," meaning they do not harm consumers, Amiji says.

"So until somebody does a study to see if they are actually providing more benefit than a placebo, we don't know whether they are working or not."

Talk to your doctor

Before experimenting with different medications to relieve nasal congestion, sufferers should check in with their doctor, Amiji says.



Stuffy noses could be caused by a variety of things, including allergies, infections and inflammation, he says.

"The most important thing is really knowing what the underlying cause is because nasal congestion is a symptom, not the disease. It's better to treat the underlying conditions as opposed to just continuing to treat nasal congestion."

Provided by Northeastern University

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