

FDA conclusion that oral phenylephrine is ineffective means consumers need to rethink medications

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The ramp-up to cold and flu season is a bad time for consumers to learn

that some of their most trusted go-to products don't actually work.

An advisory committee to the [U.S. Food and Drug Administration](#) concluded unanimously in September 2023 that phenylephrine—an active ingredient found in popular over-the-counter cough and cold products such as Sudafed PE, Theraflu and NyQuil Severe Cold and Flu—works no better than a placebo when taken orally. The 2023 FDA [advisory panel](#) met to review growing evidence that oral phenylephrine is an ineffective treatment for nasal congestion. The committee did not review the effectiveness of phenylephrine nasal spray.

In response, CVS, one of the largest pharmacy chains in America, announced that they will [no longer sell products](#) that contain oral phenylephrine as the only active ingredient in its community pharmacies.

To the millions of Americans who will suffer from colds with stuffy noses this fall and winter—many of whom have used products containing phenylephrine for years—the panel's decision may be startling.

Consumers are likely wondering whether they should stop using over-the-counter products containing phenylephrine, whether the products will still be on the shelves this winter and what other options they might have. Consumers may also question whether combination cough, cold and flu products will still be safe and effective for use at home.

As the FDA considers the advisory committee's conclusions, oral phenylephrine will still likely be sold at many pharmacies despite the fact that more effective nonprescription medications and nonmedication approaches to relieve congestion exist.

[As pharmacists who are focused on patient care in local communities](#), we have some advice on what to do when you need relief from cold and

flu symptoms.

The backstory

As of fall 2023, phenylephrine is listed as the sole active ingredient, or as one of the active ingredients, in thousands of over-the-counter products, including tablets, liquids, nasal sprays, gels and ointments.

The medication, when taken as an oral tablet, oral liquid or nasal spray, has long been used for the temporary relief of [sinus or nasal congestion](#) from the common cold or seasonal allergies. Phenylephrine has been the only oral decongestant on pharmacy and grocery store shelves since another popular decongestant, [pseudoephedrine](#), became more regulated and [went behind the counter in 2006](#).

The most recent analysis is not the first time an FDA advisory panel has scrutinized oral phenylephrine. A 2007 panel examining its use [concluded that more studies were needed](#) to make a final decision regarding the effectiveness of phenylephrine.

Additional studies since then showed [no difference in efficacy](#) between phenylephrine and a placebo, likely because phenylephrine taken by mouth is inactivated in the gut.

Safety concerns

No safety issues with oral phenylephrine alone were documented in the 2023 advisory panel conclusion. However, researchers and advisory panel members have raised concerns about the possibility of products containing ineffective phenylephrine remaining on pharmacy shelves.

Even if oral phenylephrine is safe, taking an ineffective medication

could cause consumers to spend money on products that work no better than a placebo. [A placebo effect](#) is a well-known phenomenon in which people taking an inactive product may perceive benefit. The placebo tablets used in the phenylephrine studies were the same or similar shape and color as the phenylephrine tablets but without the [active ingredient](#).

The panel also noted the missed opportunities for pharmacists to recommend something more effective for nasal congestion if phenylephrine remains commercially available.

Despite the advisory committee's conclusions, no official action has been taken by the FDA as of late October 2023. If the agency proposes a change in the availability of phenylephrine, consumers will be asked to weigh in prior to a final ruling.

The story behind pseudoephedrine

Luckily, the nonprescription [oral nasal decongestant pseudoephedrine](#)—which is known to be effective—has been commercially available for many years. This drug is available as a single ingredient product or in combination with other ingredients in products marketed to treat sinus congestion.

Pseudoephedrine is a nasal decongestant that is taken by mouth to relieve a stuffy nose. It works by constricting the [blood vessels](#) that become enlarged as a result of a cold, flu or seasonal allergies.

But buying products containing [pseudoephedrine](#) is not as straightforward as it sounds. Because pseudoephedrine can be used to [manufacture the street drug methamphetamine](#), the FDA requires that it [be sold behind the counter](#) and in limited amounts each day and month. It also requires photo identification at the point of sale.

If the FDA acts on the advisory committee's conclusions that oral phenylephrine is not an effective nasal decongestant, pseudoephedrine may be the only remaining oral medication available without a prescription to treat nasal congestion. Here are some [things to know about pseudoephedrine](#):

- Pseudoephedrine should not be used in doses higher than those that are recommended on the label. Use of products containing pseudoephedrine should be stopped and a health care provider consulted if dizziness, nervousness or sleeplessness occurs.
- Pseudoephedrine should not be used by consumers with [heart disease](#), [high blood pressure](#), thyroid disease, diabetes or an enlarged prostate without talking with a [health care provider](#) like a pharmacist or a physician.
- Products with pseudoephedrine should not be used while taking, or within two weeks of stopping, a prescription monoamine oxidase inhibitor, which is most commonly used to treat for depression or Parkinson's disease.

Other treatments

In addition to oral pseudoephedrine, medicated nasal sprays—including those containing phenylephrine or oxymetazoline as active ingredients—can also relieve [nasal congestion](#). These products are sold under the brand name Afrin and others.

However, [medications are not the only way to relieve congestion](#). Some non-drug approaches include hot, steamy showers, [safe use of neti pots](#), vaporizers or humidifiers, saline [nasal spray](#) and applying a warm, moist washcloth to the face. All of these non-drug approaches can help sooth the nasal passage to provide temporary relief from congestion. If symptoms of congestion continue for more than two weeks, or if signs of an infection arise, go see your doctor.

Since products containing oral phenylephrine will remain on the market for the time being, it is critical for consumers to read the labels of over-the-counter products and review the active ingredients and their risks.

You should talk with your pharmacist about your symptoms, medical conditions and the other medications you're taking prior to purchasing any over-the-counter product. Your pharmacist will help you determine if your symptoms can be managed with self-care or if you need to see a physician.

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