

# Why Are Certain Cold Medicines Being Removed From Store Shelves?

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## STORY AT-A-GLANCE

- › France's medicines agency has warned people not to take pseudoephedrine-containing drugs due to stroke risks
- › The European Medicines Agency's (EMA) safety committee – Pharmacovigilance Risk Assessment Committee, or PRAC – has started a safety review into the drugs
- › PRAC's review was prompted by cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) reported after use of pseudoephedrine-containing drugs
- › The potentially life-threatening conditions involve reduced blood supply, or ischemia, to the brain and may cause symptoms such as headache, nausea and seizures
- › Depending on the outcome of the review, pseudoephedrine-containing medicines, which include brand names Sudafed and Galpseud, in the European Union could be withdrawn from the market

Over-the-counter decongestants containing pseudoephedrine are commonly used to relieve stuffy noses due to colds, flu or allergies. But the drugs, which include brand names Sudafed and Galpseud, can cause life-threatening complications, including heart attack and stroke.

The risk of serious adverse events is concerning enough that France's medicines agency has warned people not to take pseudoephedrine-containing drugs,<sup>1</sup> and the European

Medicines Agency's (EMA) safety committee – Pharmacovigilance Risk Assessment Committee, or PRAC – has started a safety review.<sup>2</sup>

## **Cold Medicines May Reduce Blood Supply to the Brain**

PRAC's review was prompted by cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) reported after use of pseudoephedrine-containing drugs.

The potentially life-threatening conditions involve reduced blood supply, or ischemia, to the brain and may cause symptoms such as headache, nausea and seizures.<sup>3</sup> PRES may also cause confusion and blurred vision, while RCVS is associated with severe thunderclap headaches that may reoccur for weeks.<sup>4</sup>

Depending on the outcome of the review, pseudoephedrine-containing medicines in the European Union could be withdrawn from the market. The product information for such drugs already warns of an increased risk of cardiovascular and cerebrovascular ischemic events such as heart attack and stroke, which involve ischemia in the heart and brain.<sup>5</sup>

"The message is clear. Do not use them. We do not risk getting a stroke for a stuffy nose," Christelle Ratignier-Carbonneil, director of France's National Agency for the Safety of Medicines and Health Products (ANSM), told the media.<sup>6</sup>

In the EU, pseudoephedrine-containing medications are sold under brand names including Actifed, Aerinaze, Aspirin Complex, Clarinase, Humex rhume, and Nurofen Cold and Flu.<sup>7</sup> In the U.S., they include:<sup>8</sup>

Biofed	Contac
Dimetapp Decongestant	Pediacare Decongestant Infants
Sudafed	Simply Stuffy

## **Pseudoephedrine Causes Blood Vessels to Narrow**

Pseudoephedrine stimulates nerve endings to release noradrenaline, a chemical that causes blood vessels to narrow. "This reduces the amount of fluid released from the vessels, resulting in less swelling and less mucus production in the nose," EMA states.<sup>9</sup>

The problem is that this effect isn't restricted to your nose. Blood vessels throughout your body may be affected. One study found pseudoephedrine increased systolic blood pressure and heart rate, with higher doses and immediate-release preparations linked with the greatest blood pressure increases.<sup>10</sup>

Pseudoephedrine may also be used in the manufacture of crystal methamphetamine, which is why medications that contain it are often sold behind the counter and require an ID to be presented before purchase.

The Combat Methamphetamine Epidemic Act in 2005 states pharmacies must keep logs of pseudoephedrine purchases and set limits on how many such products one person can make in a day.<sup>11</sup>

While phenylephrine is sometimes used to replace pseudoephedrine in nasal decongestants,<sup>12</sup> it comes with its own host of problems. Not only did the U.S. Food and Drug Administration rule that phenylephrine is not effective as a nasal decongestant,<sup>13</sup> but it's been linked with intracerebral hemorrhage, a subtype of stroke.<sup>14</sup> Following the revelation that phenylephrine is ineffective, drug store chain CVS began pulling some of the cold medications from store shelves.<sup>15</sup>

Further, both phenylephrine and pseudoephedrine are amphetamine-like sympathomimetics and may cause similar effects. According to a study published in *The Journal of Stroke and Cerebrovascular Diseases*:<sup>16</sup>

*"It is scientifically plausible that phenylephrine may cause strokes, consistent with the pharmacological properties and adverse event profiles of similar amphetamine-like sympathomimetics.*

*As reversible cerebral vasoconstriction syndrome has been well-described in association with over-the-counter sympathomimetics, a likely, although not definitive, causal relationship between phenylephrine and intracerebral hemorrhage is proposed."*

## **Pseudoephedrine Linked to Cardiac Arrhythmia, Digestive Issues and More**

Pseudoephedrine has a history of adverse effects, many serious. In addition to increased blood pressure, heart attack, non-convulsive epileptic states – a prolonged seizure that manifests as altered mental state – convulsions and strange behaviors have been reported with its use. The risks may occur after even a single dose or after several days of use.<sup>17</sup>

Other adverse effects linked to pseudoephedrine include central nervous stimulation resulting in sleep disturbances, anxiety muscle tremors and confusion, digestive tract dysfunction such as nausea, vomiting and decreased appetite, urination disorders, allergic reactions and psychological dependence.<sup>18</sup>

Further, taking pseudoephedrine for more than seven days increases your risk for headaches, insomnia, increased blood pressure, fast heart rate, hallucinations and seizures.<sup>19</sup> And even a single dose may induce simultaneous bilateral acute angle closure crisis (AACC), which is considered a "sight-threatening ocular emergency."<sup>20</sup>

The drug also has addictive potential. At least one case report exists involving a woman who used pseudoephedrine for five years in increasing doses due to its euphoric effects. When the drug was suddenly discontinued, she experienced fatigue, depression and visual hallucinations. Other significant adverse effects have also been reported. According to the International Journal of Molecular Sciences:<sup>21</sup>

*"A 2003 French study analyzed adverse events with intranasal decongestants reported to regional pharmacovigilance centers by healthcare professionals. There were 22 episodes of arterial hypertension, 15 cases of convulsions and 4 cases of stroke after oral administration of drugs containing pseudoephedrine.*

*It can also induce ischemic colitis when used for as little as 3 days or up to 2 years, in a dose range of 60 to 900 mg/day. Less common adverse effects are skin reactions – cases of scarlet fever-like rash, erythematous spots, skin exfoliation of the palms and soles of the feet, and Baboon syndrome, clinically manifested by a rash mainly on the buttocks and within the larger folds of skin, have been reported.*

*When used in therapeutic doses, PSE [pseudoephedrine] may be responsible, especially in children, for the occurrence of pain and dizziness, increased heart rate, excessive agitation, insomnia and hallucinations. "Parasitic" hallucinoses (attacking spiders and insects) have been observed in children after taking an OTC (over-the-counter) drug containing pseudoephedrine and triprolidine ..."*

## **Scientists Call for Pseudoephedrine Ban**

In addition to use as a decongestant, pseudoephedrine has also been heralded as an obesity drug due to its appetite-reducing effects. It decreases appetite by inhibiting neurons in the hypothalamic paraventricular nucleus, which regulates satiety.<sup>22</sup>

However, although pseudoephedrine reduces fat accumulation, it has a "significantly unbalanced risk/benefit profile" and isn't safe, particularly in obese patients. Writing in *Reviews in Endocrine and Metabolic Disorders*, Italian researchers noted:<sup>23</sup>

*"When compared to other pharmacological options for the treatment of obesity, the ... evidence suggests that pseudoephedrine is absolutely contraindicated, in addition to pregnancy and breastfeeding, in all pre-existing cardiovascular and neuropsychiatric diseases.*

*At any rate, risks arising from the use of pseudoephedrine depend significantly upon individual susceptibility, which, at the present state of knowledge, is not known, and, therefore, scarcely predictable, for all compounds of this class."*

French researchers also concluded in 2015 that the compound should be banned over-the-counter due to its significant risks:<sup>24</sup>

*"[D]ue to unpredictable severe cardiovascular and neurological adverse events that may occur even at low dose and in the absence of any pre-existing pathology, they should not be prescribed for the common cold, and ENT physicians must carefully weigh the risk/benefit ratio in patients with allergic rhinitis. Distribution should be regulated and over-the-counter sales banned."*

## **People With These Underlying Health Conditions Shouldn't Use Decongestants**

Over-the-counter decongestants are also not recommended for people with high blood pressure, diabetes, benign prostatic hyperplasia, ischemic heart problems, thyroid disorders, glaucoma or seizures. And there's also a risk of rebound rhinitis – a worsening of symptoms that may occur with the use of decongestant nasal sprays. According to the Mayo Clinic:<sup>25</sup>

*"Using nonprescription decongestant nasal sprays (Afrin, Dristan, others) for more than three or four days can cause even worse nasal congestion once the decongestant wears off (rebound rhinitis). All too often, people think their colds are getting worse, so they increase their use of nasal spray, leading to a downward spiral of medication use and worsening congestion."*

Decongestants like pseudoephedrine are often combined with other cough and cold medications, including cough suppressants, antihistamines and expectorants. But each comes with its own risks and downsides:

- **Cough suppressants** — A common active ingredient in cough suppressants is dextromethorphan, but evidence of its effectiveness is weak.<sup>26</sup>
- **Antihistamines** — Research has found that while antihistamines may help reduce symptoms, the risks far outweigh the benefits, particularly in children.<sup>27</sup> For instance, promethazine, an antihistamine used to block allergic reactions, sometimes found in cough medicines, has a direct central effect and comes with side effects such as sedation, disorientation, hallucinations, muscle spasms and catatonic states.<sup>28</sup>
- **Expectorants** — The active ingredient in expectorants, guaifenesin, is marketed under the brand name Robitussin. Despite its broad use, studies have been inconsistent in supporting its effectiveness as an expectorant.<sup>29</sup>

## Safer Options for a Stuffy Nose

While a stuffy nose is uncomfortable, there's no reason to risk a serious health problem to find relief. Many natural options to relieve congestion exist. Peppermint oil, for instance, has expectorant and decongestant properties<sup>30</sup> that can help clear up phlegm in the respiratory tract. Try using a few drops mixed with coconut oil for a massage, or place three or four drops into an essential oil diffuser.

You can also try steam inhalation by placing three to seven drops of peppermint essential oil into boiling water, then covering your head with a towel and breathing through your nose (keep your eyes closed and be careful not to get burned).

Nasal irrigation, sometimes referred to as nasal lavage, is another effective treatment for nasal disease, helping to clear nasal secretion, improve nasal congestion and improve sinus pain, headache, taste and smell, and even sleep quality.<sup>31</sup> Nasal irrigation is a relatively popular method for relieving cold symptoms, often via the use of a neti pot, with roots in the traditional Indian health care system.

Irrigating the nasal passages with saline is used in traditional yoga practice, where it's known as jala-neti.<sup>32</sup> It involves the use of a saline solution in teapot-like device, used to

flush out the nose and sinus cavities. After inserting the end of the pot in one side of your nose, the solution moves through your sinuses and out the other nostril. A bulb syringe or squeeze bottle can also be used.

Traditionally, slightly warm saline water — a solution of 2.5 grams of salt in 500 milliliters of water — is recommended for nasal irrigation.<sup>33</sup> For additional antimicrobial action, povidone iodine (0.5% to 1%) can be added to the saline solution. Nasal irrigation is effective for relieving nasal congestion<sup>34</sup> without the risks posed by pseudoephedrine.

If you're thinking of making your own saline solution, be sure to use only distilled, sterile or cooled, boiled water. Tap water can contain bacteria and protozoa that can be harmful if they receive access to your nasal passages,<sup>35</sup> so unboiled tap water should not be used for this purpose.

## Sources and References

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- <sup>1, 6, 12</sup> [Euronews.next October 23, 2023](#)
- <sup>2, 3, 5, 7, 9</sup> [European Medicines Agency October 2, 2023](#)
- <sup>4</sup> [BBC News February 23, 2023](#)
- <sup>8</sup> [Mayo Clinic Pseudoephedrine](#)
- <sup>10</sup> [Arch Intern Med. 2005;165\(15\):1686-1694. doi: 10.1001/archinte.165.15.1686](#)
- <sup>11</sup> [National Institute on Drug Abuse, Methamphetamine Research Report](#)
- <sup>13</sup> [U.S. FDA September 14, 2023](#)
- <sup>14, 16</sup> [J Stroke Cerebrovasc Dis. 2014 Oct; 23\(9\): 2296–2300](#)
- <sup>15</sup> [AP October 20, 2023](#)
- <sup>17, 18, 21</sup> [Int J Mol Sci. 2021 May; 22\(10\): 5146](#)
- <sup>19</sup> [International Journal of Molecular Sciences, 2021;22\(10\) Section 8. Overdose](#)
- <sup>20</sup> [Case Rep Ophthalmol. 2019 Sep-Dec; 10\(3\): 365–368](#)
- <sup>22, 23</sup> [Rev Endocr Metab Disord. 2021; 22\(4\): 1013–1025](#)
- <sup>24</sup> [European Annals of Otorhinolaryngology, Head and Neck Diseases February 2015, Volume 132, Issue 1, Pages 31-34](#)
- <sup>25</sup> [Mayo Clinic December 29, 2015](#)
- <sup>26</sup> [American Family Physician, 2008;78\(1\)](#)
- <sup>27</sup> [Cochrane Database of Systematic Reviews, April 16, 2008;2](#)
- <sup>28</sup> [RxList, Promethazine](#)
- <sup>29</sup> [Respir Care. 2014 May;59\(5\):631-6. doi: 10.4187/respcare.02640. Epub 2013 Sep 3](#)
- <sup>30</sup> [Mount Sinai, Peppermint Colds and flu section](#)
- <sup>31</sup> [PeerJ. 2019 May 27;7:e7000. doi: 10.7717/peerj.7000. eCollection 2019](#)

- <sup>32</sup> Explore (NY). 2021 March-April; 17(2): 127–129
- <sup>33</sup> Indian J Otolaryngol Head Neck Surg. 2021 Oct 17: 1–7
- <sup>34</sup> Indian J Otolaryngol Head Neck Surg. 2019 Nov; 71(Suppl 3): 1718–1726
- <sup>35</sup> Centers for Disease Control and Prevention, Parasites - Naegleria fowleri - Primary Amebic Meningoencephalitis (PAM)