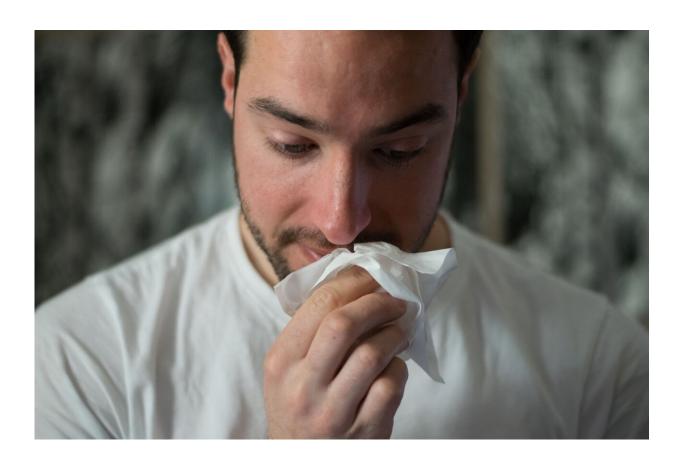


Popular nasal decongestant found to be ineffective by US drugs regulator—what it means for the UK

October 23 2023, by Philip Crilly



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An advisory panel of the US Food and Drug Administration has found that a drug used in the majority of cold and flu products to treat blocked



noses does not work.

The panel noted that <u>phenylephrine</u>, in tablet, capsule and <u>liquid form</u>, did not relieve <u>nasal congestion</u>. It did, however, point out that despite being ineffective, there were no concerns about its safety so people should not panic if they have been taking the <u>drug</u>.

In addition, the findings do not apply to the <u>nasal spray</u> version of the drug, which the panel did deem to be effective.

Phenylephrine first began to be sold in the UK in the 1970s. It acts by shrinking the <u>blood vessels</u> in the nose to improve air flow, thereby making it easier to breathe.

Today, phenylephrine is found in many of the UK's staple cold and flu products, including Lemsip, Beechams, Sudafed and Benylin. Its popularity was cemented when another decongestant, pseudoephedrine, had <u>restrictions placed on its sales in 2008</u> due to concerns about misuse, and phenylephrine was chosen as the main decongestant for many products.

Concerns first raised in 2007

Given that it has been used since the 1970s, many will be wondering why it is only now that phenylephrine is being deemed to be ineffective. The answer lies in the way the effectiveness of the drug is measured today compared with when it was first launched, with concerns first being raised in 2007.

When taking any <u>oral medicine</u>—tablet, capsule, liquid—the drug has to pass through the stomach before being able to have an effect. Some of the drug is broken down in the stomach, with the remainder being used by our bodies to treat our symptoms. Early research for phenylephrine



showed that a third of the drug remained after leaving the stomach. This was deemed enough to affect nasal congestion.

More recent research, however, used more accurate methods and noted that less than 1% of phenylephrine remained after leaving the stomach. This figure was deemed too low for the drug to have any meaningful effect.

It is for this reason that only the oral forms of the medication are deemed to be ineffective, as the nasal spray does not have to go through the stomach and acts directly where it is needed.

Today, there are also more accurate ways to measure improvements in nasal congestion compared with when phenylephrine was first tested, and, again, oral phenylephrine did not show any effect at all using these newer methods.

So, are we about to see many of our family favorite medicines removed from pharmacy shelves?

In the US, the <u>FDA states</u> that it needs to consider the findings of the advisory panel before taking any action. However, CVS Pharmacy, the <u>largest chemist chain</u> in the US, has announced it will <u>remove from its shelves</u> certain oral cough and cold products that have phenylephrine as the only active ingredient.

In the UK, the drug's regulator, the MHRA, has issued a statement. Alison Cave, the agency's chief safety officer, said, "There have been no new safety concerns identified with phenylephrine-containing products and people can continue to use as directed."

With temperatures getting colder and the cold and flu season fast approaching, many people may now be confused about what to do for



their stuffy noses. It is important to remember that neither the US nor the UK drug regulators have suggested removing oral phenylephrine from pharmacy shelves.

For those who want to try alternatives, however, the nasal spray version of phenylephrine is still deemed to be effective. Also, pseudoephedrine tablets from behind the pharmacy counter, as well as steroid nasal sprays, saline nasal sprays, and steam inhalation therapy with menthol vapor rubs, are other options.

As ever, the local pharmacist is the best person to speak to about any drug queries, and for advice on the best treatment options for the cold and flu season ahead.

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