

Common cold meds may pose health threats

March 19 2014, by Steven Reinberg, Healthday Reporter



Interaction of two ingredients could cause serious side effects, researchers say .

(HealthDay)—Over-the-counter sinus and pain remedies that combine two common ingredients—phenylephrine and acetaminophen—might cause serious side effects such as high blood pressure, dizziness and tremors, New Zealand researchers warn.

These [side effects](#) occur because [acetaminophen](#) (the main ingredient in Tylenol) boosts the effects of phenylephrine, according to a report in the March 20 issue of the *New England Journal of Medicine*.

Products containing this drug combination include Tylenol Sinus, Sudafed PE Sinus, Benadryl Allergy Plus Sinus and Excedrin Sinus Headache.

"What we found was surprising because it hasn't been studied or reported," said lead researcher Hartley Atkinson, managing director of AFT Pharmaceuticals, Ltd., in Auckland.

Phenylephrine, which replaced pseudoephedrine in many over-the-counter medications, relieves nasal congestion from colds, allergies and hay fever. Pseudoephedrine had become a source for creating the illegal drug methamphetamine, and the U.S. Food and Drug Administration asked manufacturers to voluntarily remove it from their products.

When phenylephrine is combined with acetaminophen, blood levels of phenylephrine rise to four times higher than when the same amount of phenylephrine is used alone, Atkinson said.

"Basically, if you give the combination, a lot more phenylephrine absorbs into your body than what you would be expecting," Atkinson said.

Side effects can also include insomnia, headache, heart palpitations, anxiety and urine retention.

Atkinson noted that labels on products containing phenylephrine warn of possible side effects for people with heart disease or prostate problems. These warnings, however, refer only to the dose of phenylephrine approved for that product.

People with these conditions need to know that in actuality the dose might be higher, he said.

Similar reactions might occur with drugs such as vitamin C that are metabolized in the body like phenylephrine, Atkinson said.

"In a lot of countries, there are drugs that contain acetaminophen, phenylephrine and vitamin C together, which could cause an even greater interaction," he said.

Atkinson stumbled upon this drug interaction while developing a new

drug containing acetaminophen, ibuprofen (the main ingredient in Advil) and phenylephrine. Ibuprofen does not cause harmful side effects when combined with phenylephrine, he said.

This [drug interaction](#) is a problem regulatory agencies need to consider, Atkinson said.

Another expert agreed the findings are worrisome.

"This article sheds light on a previously unknown reaction of acetaminophen with phenylephrine, which essentially raises the possibility of an overdose with a single dose," said Dr. Houman Danesh, director of integrative pain management at the Icahn School of Medicine at Mount Sinai, in New York City.

"Taking medications which contain ibuprofen with phenylephrine may be safer with regards to phenylephrine toxicity," Danesh said. "However, ibuprofen has increased risks of stomach ulcers, kidney issues and hearts issues as well. So, once again, consult with your doctor."

The FDA is aware of the problem, but agency spokeswoman Andrea Fischer said it has limited ability to regulate.

"Both phenylephrine and pseudoephedrine are generally recognized as safe and effective and may be marketed without premarket approval by the FDA," Fischer said.

Likewise, it's permissible to combine either nasal decongestant with acetaminophen, she said.

According to McNeil Consumer Healthcare, the Johnson & Johnson subsidiary that makes some of these dual-ingredient remedies, combination acetaminophen-phenylephrine drugs are safe.

"Based upon clinical studies, years of use and post-marketing surveillance, we believe over-the-counter doses of acetaminophen and phenylephrine, when taken together, are considered safe," said Jodie Wertheim, a McNeil spokeswoman.

"When used as directed, over-the-counter medicines containing acetaminophen and phenylephrine are both effective and well-tolerated," she added.

Not everyone is convinced, however.

"More caution needs to be relayed to consumers," said Victoria Richards, an associate professor of medical sciences at the Frank H. Netter M.D. School of Medicine at Quinnipiac University in North Haven, Conn.

"Consumers should look at the labels carefully and talk with the pharmacist or with their doctor to understand exactly what they're taking," she said.

More information: Learn more about phenylephrine from the [U.S. National Library of Medicine](#).

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