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Common decongestant treatment labelled ‘not effective’ by FDA advisory committee

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A Food and Drug Administration (FDA) advisory committee unanimously agreed that a drug long used in common over-the-counter nasal decongestants is not effective at relieving symptoms.

After reviewing data from several studies during its Sept. 11-12 meeting, the 16 members of the Nonprescription Drugs Advisory Committee (NDAC) agreed the data do not support a dosage of 10 milligrams (mg) of orally administered phenylephrine (PE) as an effective nasal decongestant.

A majority of members also said they were not in favor of additional studies exploring the efficacy of larger doses to combat nasal congestion, with many expressing concerns of increased blood pressure with higher PE doses.

“The evidence showed that you would have to go at least over 40 mg and then you start having safety risks,” said Jennifer A. Schwartzott, M.S., patient representative of NDAC. “I think we have an ethical and moral obligation to the patients. There are other alternatives out there, and hopefully other companies will come up with new medications in the future. Given that we know what we know, I think it’s up to us to say this is where this ends.”

Recommendations from the committee will be given to FDA leadership for possible action.

A pair of citizen petitions submitted in 2007 and 2015 asked the FDA to look at the efficacy of PE as a nasal decongestant. Since then, three large clinical trials were conducted. NDAC was called to discuss whether

products containing PE should be reclassified as “not generally recognized as safe and effective” due to lack of efficacy.

According to study findings shared by FDA officials, orally administered PE is not effective as a nasal decongestant at a dosage of 10 mg every four hours or at doses up to 40 mg every four hours.

“The thing that matters when you are dosing a drug is how much of the drug gets to where it needs to be and whether it is a high enough concentration to affect the receptor that it’s trying to affect to make the change,” said Theresa Michele, M.D., director of the FDA Office of Nonprescription Drugs. “In this case, we need the drug to get to the alpha receptors in the nose so they can constrict the blood vessels and reduce the amount of congestion. The actual amount that’s absorbed is somewhat irrelevant. What we really care about is the fact that the concentration that affects the receptors is higher than the concentration that you can get into your body because it’s extensively metabolized by the intestine.”

When the drug was approved in 1976, the Drug Efficacy Study Implementation Panel published a report that concluded PE hydrochloride is “safe and effective” as an orally administered nasal decongestant for nonprescription use at the specified dosage.

Peter Starke, M.D., FAAP, lead clinical reviewer for the FDA, said the initial studies from the 1970s and the more recent trials are “markedly different.”

“Changes to drug development, clinical trial design and clinical review practices could be a whole talk in and of itself,” Dr. Starke said. “But the science has also advanced and this talk will focus on the efficacy and safety data through the lens of current best clinical drug development and review practices.”

Dr. Starke said studies conducted in 2009, 2015, 2016 and 2017-’18 showed no significant difference between PE treatments and placebo.

NDAC member Bridgette L. Jones, M.D., M.S.C.R., a professor of pediatrics at the University of Missouri-Kansas City School of Medicine, said the new data provide an opportunity for education to all age groups.

“I think with the newer studies that were done after 2007, using what’s currently the gold standards of symptom scores, we don’t see efficacy. I believe that data, I think it’s impactful and we should listen to that data,” Dr. Jones said.

She also called on FDA leaders to work with trusted partners to get the message out about accessing proven treatments, such as pseudoephedrine, which was moved behind the counter in 2006.

“I suspect there may be some people in the public who may not be aware of how to access it,” Dr. Jones said. “Making sure the message is reaching those that are in rural and underserved areas in developing plans specifically for those patient groups is important.”

Industry representatives noted PE products have high consumer satisfaction, and the oral treatments are labeled as providing only “temporary relief” from nasal congestion.