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PLEASE REVIEW Drug Information

PharmPix Clinical Department

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

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PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Oral Phenylephrine not Effective as a Decongestant

Back in September 2023 the FDA held a Non-prescription Drug Advisory Committee meeting and concluded that oral phenylephrine is ineffective as an oral nasal decongestant.

Advisory Committee Meeting

The Non-prescription Drug Advisory Committee met to discuss the effectiveness of oral phenylephrine as an active ingredient in over the counter (OTC) cough and cold products for temporary relief of congestion.

The committee discussed the efficacy and pharmacokinetic data for phenylephrine. When reviewing new data on the effectiveness of oral phenylephrine, the committee agreed that the current scientific data does not support that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant. The review of pharmacology and clinical data presented by the FDA found that the oral bioavailability of the drug is less than 1%. A mechanism potentially responsible for this may be the short half-life of active phenylephrine.

Of note, neither the FDA nor the committee raised concerns about safety issues with the use of oral phenylephrine at the recommended dose.

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.

Recommendations

Consumers should know there is a range of products that are available for temporary relief of congestion symptoms. They should be aware that some products only contain phenylephrine, while others may contain phenylephrine and another active ingredient. The consumer should read the drug facts label to determine which ingredients are in a medication, as well as important warnings and directions for use.



Additional information can be found at:

- [FDA clarifies results of recent advisory committee meeting on oral phenylephrine](#)

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). FDA clarifies results of recent advisory committee meeting on oral phenylephrine. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine>

