COMMUNICATION

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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

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.

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

Call us at 787-522-5252-Clinical Department.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

FDA Suggests Removing Nonprescription Decongestant from Market

On November 7, 2024, the FDA announced its proposal to remove over-the-counter (OTC) products that contain phenylephrine. Phenylephrine, a nasal decongestant found in nonprescription cold products, such as Mucinex and Sudafed and other products, has been deemed ineffective by the FDA.

Background:

The use of phenylephrine increased after 2006, when products containing pseudoephrine were moved behind the pharmacy counter due to their potential use in methamphetamine production. In response, many manufacturers of cold products reformulated their products with phenylephrine instead of phenylpropanolamine, ephedrine, and pseudoephedrine.

Reasoning Behind the Proposed Removal:

The FDA conducted a comprehensive review of all available data on the safety and efficacy of oral phenylephrine. This review included both historical data, which supported its approval as an effective nasal decongestant 30 years ago, and newer clinical evidence.

Additionally, the FDA held a Nonprescription Drug Advisory Committee meeting to discuss the 'Generally Recognized as Safe and Effective' status of oral phenylephrine as a nasal decongestant. After reviewing the latest scientific data, the committee concluded that the recommended OTC dosage of oral phenylephrine is not supported by current evidence as effective for the treatment of nasal congestion.

Regulatory Process:

If the FDA finalizes its decision, it will begin a multi-step process to remove OTC oral phenylephrine from the market, starting with a proposed order and a 180 day public comment period. During this time, oral phenylephrine products will remain on the market. However, following this process, this medication will most likely be removed from the OTC monograph and market.

Additional information can be found at: https://www.fda.gov/news-events/press-announcements/fda-proposes-ending-use-oral-phenylephrine-otc-monograph-nasal-decongestant-active-ingredient-after

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REFERENCES:
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2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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