March 30, 2021 COM-2021-017

DRUG SAFETY NOTIFICATION

DATE: MARCH 25, 2021

DRUG NAME: BENZEDREX (PROPYLHEXEDRINE)

DRUG INDICATION: TEMPORARY RELIEVE NASAL CONGESTION DUE TO COLDS, HAY FEVER, OR OTHER UPPER RESPIRATORY ALLERGIES

SAFETY TOPIC: FDA WARNS THAT ABUSE AND MISUSE OF PROPYLHEXEDRINE CAUSES SERIOUS HARM

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate with you with the latest up-to-date information on drug safety. For this reason, we are notifying you that the U.S. Food and Drug Administration (FDA) is warning that the abuse and misuse of the over-the-counter (OTC) nasal decongestant propylhexedrine (Benzedrex) can cause serious harm such as heart and mental health problems, which can lead to hospitalization, disability, or death. The FDA is requesting all product's manufacturers to consider product design changes that support its safe use. The FDA continues to evaluate this safety issue and will determine if additional actions are needed.

Recommendations for healthcare professionals:

- Be aware that some individuals are abusing or misusing propylhexedrine. In the event of a suspected overdose, attempt to determine whether a patient used propylhexedrine alone or with other substances. There is no specific reversal agent in cases of acute intoxication, so symptomatic and supportive care should be provided.
- Educate patients. Propylhexedrine is safe and effective when used as directed, and should only be used according to the directions on the Drug Facts label. The use by routes other than inhalation can cause serious harm and can lead to death.

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- Advise patients to talk with their healthcare provider if they have any questions or concerns.
- Advise patients to inform their healthcare provider about all the medications they are taking, including OTC medications.
- Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:
    - Complete and submit the MedWatch Online Voluntary Reporting Form online.
    - Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at MedWatch: The FDA Safety Information and Adverse Event Reporting Program and FDA's Drug Safety and Availability portal.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- Benzedrex (propylhexedrine): Drug Safety Communication. U.S. Food and Drug Administration. (2021). Retrieved March 2021, from https://www.fda.gov/safety/medical-product-safety-information/benzedrex-propylhexedrine-drug-safety-communication-fda-warns-abuse-and-misuse-nasal-decongestant.
- Serious harm from abuse/misuse of nasal decongestant propylhexedrine. U.S. Food and Drug Administration. (2021). Retrieved March 2021, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-abuse-and-misuse-nasal-decongestant-propylhexedrine-causes-serious-harm.

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