

September 28, 2020 COM-2020-073

# DRUG SAFETY NOTIFICATION



DATE: September 24, 2020

DRUG NAME: Benadryl™ (diphenhydramine)

DRUG INDICATION: Allergy symptoms relief

SAFETY TOPIC: Drug misuse in teens by "Benadryl Challenge"

## Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. For this reason, we are notifying you that on September 24, 2020, the US Food and Drug Administration (FDA) published a safety communication for Benadryl™(diphenhydramine) indicating about the serious problems related to the teen misuse sparked by the "Benadryl Challenge" promoted on social media (TikTok). Diphenhydramine is an antihistamine used to relieve symptoms due to allergies, common cold, or hay fever. The inappropriate use of this OTC product may lead to heart problems, seizures, coma, or even death.

### Recommendations for healthcare professionals:

- Encourage patients and caregivers to read and follow the
  Drug Facts Labels for the appropriate use of diphenhydramine.
- Advise patients and caregivers not to use more than the dose listed on the label to avoid serious health problems. Also, encourage them to store diphenhydramine, OTC products, and prescription medicines lock up and away from children.
- If someone takes too much diphenhydramine and presents with symptoms including hallucinations, trouble breathing, seizures, or has collapsed, get medical attention immediately or contact poison control at 1-800-222-1222 or online.

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- Report adverse events or side effects at <u>MedWatch: The FDA Safety Information and</u>
  <u>Adverse Event Reporting Program</u> by any of the following ways:
  - o 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:

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:
 <a href="https://www.pharmpix.com/providers/">https://www.pharmpix.com/providers/</a>.

Regards,

PharmPix Clinical Department

#### Reference:

FDA Drug Safety Communication. (2020). FDA warns about serious problems with high dose of the allergy medicine diphenhydramine (Benadryl). Retrieved from <a href="https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-problems-high-doses-allergy-medicine-diphenhydramine-benadryl">https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-problems-high-doses-allergy-medicine-diphenhydramine-benadryl</a>.

