Joint Meeting of the National Transportation Safety Board and Food and Drug Administration on Transportation Safety and Potentially Sedating or Impairing Medications

OTC Medicines

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November 14, 2001

OTC Antihistamines

- **For relief of:**
  - Allergy symptoms, cough, runny nose, nausea, sleeplessness
- **OTC Review:**
  - Thorough review by FDA and its Expert Panels
    - Drowsiness
      - Wide range in susceptibility
      - ≤10% - 50% experiencing drowsiness, depending on the antihistamine, the dose, and the underlying condition
    - Labeling
      - Specific drowsiness warnings for different classes of antihistamines
      - Considered in detail the potential for machinery-related accidents and drug interactions
    - **Final Determination: "Generally recognized as safe and effective"**

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01N-0397 TS7

OTC Labeling

Example of Antihistamine Drowsiness Warning

Warnings for OTC Ethanolamine Antihistamines
Excerpt from the OTC "Drug Facts" Label

When using this product:

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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Ten-year Post-marketing Surveillance Analysis: Antihistamines

- **Antihistamines: OTC or Rx**
  - CHPA Post-marketing AER Profile Study
    - Search by ingredient and brand name
      - Brompheniramine
      - Dexbrompheniramine
      - Chlorpheniramine
      - Dexchlorpheniramine
      - Diphenhydramine
      - Doxylamine
      - Phenindamine
      - Pyrilamine
      - Triprolidine
      - Cyclizine
      - Dimenhydrinate
      - Meclizine
    - Includes all combination products

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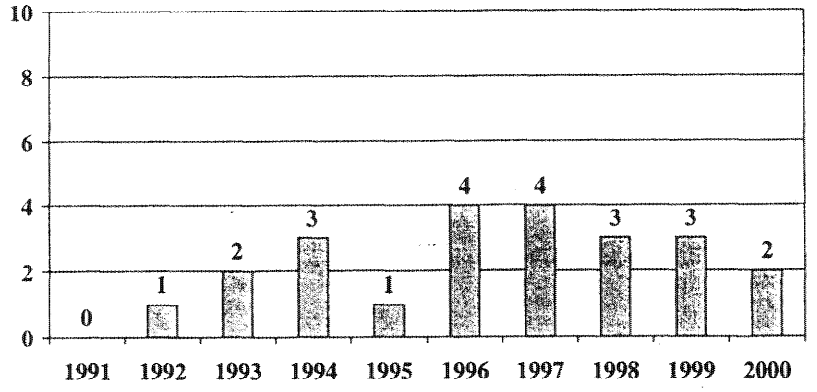
Total Adverse Experience Reports with an "Accident" Term for Persons ≥ 16 years of age



OTC and Rx AERs w/ AH as Primary Suspect (PS)	18
OTC and Rx AERs w/.AH as Secondary Suspect (SS)	5
OTC Packages Sold Over 10 years (1/1/91-12/31/00)/adults	~850 million

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New OTC Label

Pre Drug Facts Label

INDICATIONS: Temporarily relieves runny nose and sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies.
DIRECTIONS: Follow dosage directions below, or use as directed by your doctor. Take every 4 to 6 hours. Do not take more than 6 tablets in 24 hours.

AGE	DOSAGE
adults and children 12 years of age and over	1 tablet
children under 12 years of age	Consult a doctor

WARNINGS: May cause excitability especially in children. Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland. May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.
ACTIVE INGREDIENT: Each tablet contains: Ethanolamine x mg. Also contains: (inactive ingredients are listed)
Store at 59° to 77° in a dry place.
Protect from light.

Drug Facts

Active Ingredient (in each tablet) — **Purpose**
Ethanolamine x mg ..... Antihistamine

Uses
- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat

Warnings
Ask a doctor before use if you have
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- take every 4 to 6 hours
- do not take more than 6 tablets in 24 hours

adults and children 12 years of age and over	1 tablet
children under 12 years of age	Consult a doctor

Other information
- store at 59° to 77°F in a dry place
- protect from light

Inactive ingredients (inactive ingredients are listed)

Questions?

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Conclusions

- OTC antihistamines have a demonstrated history of safe and effective use, when used according to label directions.
- OTC antihistamines are appropriately and adequately labeled with a warning for drowsiness.
- "Drug Facts" labeling will make the warning label even better.
- CHPA believes that it is important to maintain an on-going program of consumer education on the importance of reading the entire OTC label.

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