

# Key Aspects of the Proposed OTC Drug Label

This proposed prototype label would make it easier for consumers to read, understand and, it is hoped, follow the important information on OTC drug labels.

The outline format is designed to cue consumers to the information's organization, increasing their attention to the main messages.

Other proposed improvements include easier-to-read 6-point Helvetica type; distinct sections presented in a standard order; and adequate spacing between letters, words and lines of text. The required use of uppercase and lowercase letters and dark type on a light background also would improve readability.

## Proposed Format

Active ingredients would be listed alphabetically with their quantity per dosage unit (in this case a tablet). Consumers could clearly see the purpose of each ingredient.

The list of uses in the next section would help consumers readily compare products to find the appropriate medicine for their specific symptoms.

Placing all warnings in one continuous space would help ensure that every warning is noticed.

Active Ingredient (In Each Tablet)	Purpose
Chlorpheniramine Maleate 4 mg.....	Antihistamine

**Uses:** for the temporary relief of these symptoms of hay fever

- ▶ sneezing
- ▶ runny nose
- ▶ itchy, watery eyes

**Warnings**

**Ask a Doctor Before Use If You Have:**

- ▶ glaucoma
- ▶ a breathing problem such as emphysema or chronic bronchitis
- ▶ difficulty in urination due to enlargement of the prostate gland

**If You Are:**

- ▶ taking sedatives or tranquilizers

**When Using This Product:**

- ▶ marked drowsiness may occur
- ▶ alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- ▶ avoid alcoholic beverages
- ▶ 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 right away.

**Directions:**

Adults and children over 12 years:	Take 1 tablet every 4 to 6 hours as needed. Do not take more than 6 tablets in 24 hours.
Children 6 to under 12 years:	Take 1/2 tablet every 4 to 6 hours as needed. Do not take more than 3 tablets in 24 hours.
Children under 6 years:	Ask a doctor.

Headings and subheadings, boldface type, bullets, and simpler, concise language would emphasize and clarify important information.

## Existing Label

# Allergy Tablets

**INDICATIONS:** Provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies.

**DIRECTIONS:** Adults and children 12 years and over—1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours or as directed by a physician. Children 6 to 11 years—one half the adult dose (break tablet in half) every 4 to 6 hours, not to exceed 3 whole tablets in 24 hours. For children under 6 years, consult a physician.

**EACH TABLET CONTAINS:** Chlorpheniramine Maleate 4 mg. **May also contain** (may differ from brand): D&C Yellow No. 10, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch.

**WARNINGS:** May cause excitability especially in children. Do not take this product unless directed by a physician, 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 drowsiness; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages, and do not take this product if you are taking sedatives or tranquilizers without first consulting your physician. 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.

Store at controlled room temperature 2°-30°C (36°-86°F).  
 Use by expiration date printed on package.  
 Protect from excessive moisture.  
 For better identification keep tablets in carton until used.

N  
3 111111 11111 B

Made in U.S.A.