

US Food and Drug Administration, Original and Revised 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.

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Made in U.S.A.

Is “indications” a technical term? Is it as clear as “Uses”?

“Each Tablet Contains” does not provide the same specific information as “Active Ingredient.”

Notice how much clearer the warning are in the new label.

The borders make this label easier to navigate

When paragraphs are changed to lists, each item on the list becomes a direct object for the verb in the introductory clause. Unnecessary words are deleted.

## Drug Facts

Active ingredient (in each tablet)	Purpose
Chlorpheniramine maleate 2 mg.....	Antihistamine

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

**Warnings**  
Ask a doctor before use if you have  
 ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis  
 ■ trouble urinating due to an enlarged prostate gland  
 Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives  
 When using this product  
 ■ drowsiness may occur ■ avoid alcoholic drinks  
 ■ alcohol, sedatives, and tranquilizers may increase drowsiness  
 ■ be careful 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	
adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

**Drug Facts** (continued)

**Other information** ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

**Inactive ingredients** D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Critical information that may be needed quickly in an emergency is in bold.

Notice that “effective,” in the original “Indications,” has been deleted in the revised “Uses.” Why would the FDA want that word removed?

“Inactive ingredients” are now clearly labeled.

The revised “Directions” chart is much easier to use than the “Directions” paragraph in the original.