

Effective Date: May 16, 2002  
for most OTC drug products.  
U.S. Food and Drug Administration

# WHAT'S ON THE NEW LABEL

All nonprescription, over-the-counter (OTC) medicine labels have detailed usage and warning information so consumers can properly choose and use the products.

Below is an example of what the new OTC medicine label looks like.

## ACTIVE INGREDIENT

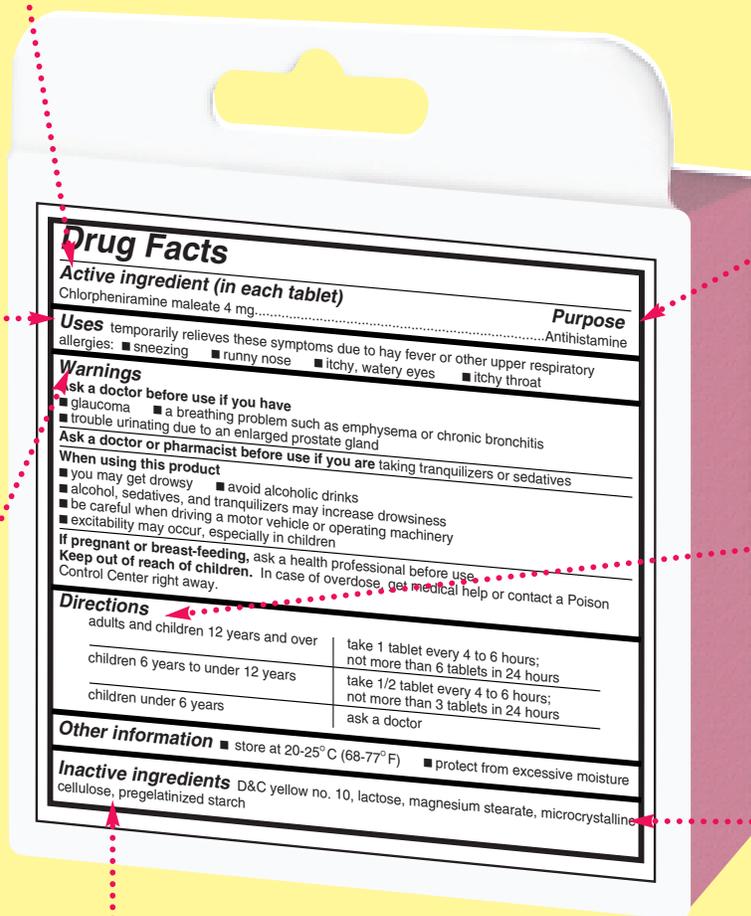
Therapeutic substance in product; amount of active ingredient per unit

## USES

Symptoms or diseases the product will treat or prevent

## WARNINGS

When not to use the product; conditions that may require advice from a doctor before taking the product; possible interactions or side effects; when to stop taking the product and when to contact a doctor; if you are pregnant or breastfeeding, seek guidance from a health care professional; keep product out of children's reach



## PURPOSE

Product action or category (such as an antihistamine, antacid, or cough suppressant)

## DIRECTIONS

Specific age categories, how much to take, how to take, and how often and how long to take

## OTHER INFORMATION

How to store the product properly and required information about certain ingredients (such as the amount of calcium, potassium, or sodium the product contains)

## INACTIVE INGREDIENTS

Substances such as colors or flavors

*The new Drug Facts labeling requirements do not apply to dietary supplements, which are regulated as food products, and are labeled with a Supplement Facts panel.*

For more information visit: [www.fda.gov/cder](http://www.fda.gov/cder) or call 1-888-INFO-FDA

