

ALLERGY AND STUFFY NOSE- chlorpheniramine maleate and phenylephrine hydrochloride liquid

Accudial Pharmaceutical, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

**Children's
ACCUDIAL**

ALLERGY & STUFFY NOSE

Drug Facts

<i>Active ingredients (in each 5 mL, 1 teaspoonful)</i>	<i>Purposes</i>
Chlorpheniramine maleate 1 mg	Antihistamine
Phenylephrine HCl 2.5 mg	Nasal decongestant

Uses

- temporarily relieves
 - itchy, watery eyes
 - runny nose
 - itchy nose or throat
 - sneezing
 - nasal and sinus congestion as may occur with a cold

Warnings

Do not use

- in a child under 4 years of age
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if the child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- for the purpose of making your child sleepy

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as asthma or chronic bronchitis

Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- marked drowsiness may occur

- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days or occur with a fever. These could be signs of a serious condition.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- may be given every 4 hours. Do not give more than 6 doses in 24 hours unless directed by a doctor.
- to find right dose, use rotating bottle label to dose by weight; otherwise, use chart below to dose by age.
- specifically designed for use with enclosed dosing spoon. Use only enclosed dosing spoon to dose this product. Do not use any other dosing device.

Age	Dose
children under 4 years of age	do not use
children 4 to under 6 years of age	do not use unless directed by a doctor
children 6 to under 12 years of age	1-2 tsp. (5-10 mL)

Other information

- **each teaspoonful contains:** sodium 3 mg
- store at controlled room temperature 20°-25°C (68°-77°F)

Inactive ingredients

artificial flavor, benzoic acid, citric acid, disodium EDTA, FD&C yellow #6, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Questions?

877-434-2036

PRINCIPAL DISPLAY PANEL - 118 mL Carton

**CHILDREN'S
ACCUDIAL**

ROTATING DOSING LABEL

**Allergy
& Stuffy Nose**

**ACCURATE DOSING
BY WEIGHT**

**Chlorpheniramine maleate
(Antihistamine)**

Phenylephrine HCl

(Nasal Decongestant)

Itchy, Watery Eyes

Runny Nose

Stuffy Nose

Sneezing

For Ages 6 to under 12

Compares to

Children's Triaminic[®]

Cold & Allergy.

ORANGE

FLAVOR

4 FL. OZ.

(118 mL)

NDC 45014-141-04



ALLERGY AND STUFFY NOSE

chlorpheniramine maleate and phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45014-141
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Chlorpheniramine Maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine -	Chlorpheniramine Maleate	1 mg in 5 mL

UNII:3U6IO1965U)	Chlorpheniramine maleate	1 mg in 5 mL		
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg in 5 mL		
Inactive Ingredients				
Ingredient Name		Strength		
Orange (UNII: 5EVU04N5QU)				
Benzoic Acid (UNII: 8SKN0B0MIM)				
Citric Acid Monohydrate (UNII: 2968PHW8QP)				
Edetate Disodium (UNII: 7FLD91C86K)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
Propylene Glycol (UNII: 6DC9Q167V3)				
Water (UNII: 059QF0K00R)				
Sodium Citrate (UNII: 1Q73Q2JULR)				
Saccharin Sodium (UNII: SB8ZUX40TY)				
Sorbitol (UNII: 506T60A25R)				
Product Characteristics				
Color	ORANGE	Score		
Shape		Size		
Flavor	ORANGE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45014-141-04	118 mL in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	11/11/2009		

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Revised: 11/2009

Accudial Pharmaceutical, Inc.