**RUNNY NOSE AND COUGH- brompheniramine maleate, dextromethorphan hydrobromide 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.*

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**Children's**
**ACCUDIAL**

**RUNNY NOSE & COUGH**

***Drug Facts***

| ***Active ingredients (in each 5 mL tsp)*** | ***Purposes*** |
|---|---|
| Brompheniramine maleate, USP .5 mg | Antihistamine |
| Dextromethorphan HBr, USP 5 mg | Cough suppressant |
| Phenylephrine HCl, USP 1.25 mg | Nasal decongestant |

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold, and nasal congestion due to the common cold, hay fever, or other upper respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis):
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
- temporarily restores freer breathing through the nose

**Warnings**

**Do not use**

- to sedate a child or to make a child sleepy
- if you are now 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if the child has**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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

**When using this product**

- **do not use more than directed**
- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

**Stop use and ask a doctor if**

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**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**

- do not take more than 4 doses in any 24-hour period
- 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 6 to under 12 years | 1½-3 tsp. (7.5-15 mL) every 6 hours |
| children under 6 years | do not use |

**Other information**

- **each teaspoon contains:** sodium 3 mg
- store at 20°-25°C (68°-77°F)

**Inactive ingredients**

artificial flavor, citric acid, FD&C blue no. 1, FD&C red no. 40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol.

**Questions?**

**877-434-2036**

**PRINCIPAL DISPLAY PANEL - 118 mL Carton**

**CHILDREN'S**
ACCU**DIAL**

**ROTATING DOSING LABEL**

**ACCURATE DOSING BY WEIGHT**

**Nasal Decongestant**
**Antihistamine**
**Cough Suppressant**

RELIEVES
**Nasal Congestion**
**Runny Nose**
**Itchy, Watery Eyes**
**Coughing, Sneezing**

**For Ages 6 to under 12**

Alcohol Free
*Compares to the active ingredients in Children's Dimetapp® Cold & Cough.*

**GRAPE FLAVOR**

4 FL. OZ.
(118 mL)
NDC 45014-153-04

**Runny Nose & Cough**


# RUNNY NOSE AND COUGH

brompheniramine maleate, dextromethorphan hydrobromide and phenylephrine hydrochloride liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:45014-153 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |

| | | |
|---|---|---|
| **Brompheniramine Maleate** (UNII: IXA7C9ZN03) (Brompheniramine - UNII:H57G17P2FN) | Brompheniramine Maleate | 0.5 mg in 5 mL |
| **Dextromethorphan Hydrobromide** (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS) | Dextromethorphan Hydrobromide | 5 mg in 5 mL |
| **Phenylephrine Hydrochloride** (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV) | Phenylephrine Hydrochloride | 1.25 mg in 5 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **Grape** (UNII: 6X543N684K) | |
| **Citric Acid Monohydrate** (UNII: 2968PHW8QP) | |
| **FD&C Blue No. 1** (UNII: H3R47K3TBD) | |
| **FD&C Red No. 40** (UNII: WZB9127XOA) | |
| **Glycerin** (UNII: PDC6A3C0OX) | |
| **Propylene Glycol** (UNII: 6DC9Q167V3) | |
| **Water** (UNII: 059QF0KO0R) | |
| **Sodium Benzoate** (UNII: OJ245FE5EU) | |
| **Sodium Citrate** (UNII: 1Q73Q2JULR) | |
| **Saccharin Sodium** (UNII: SB8ZUX40TY) | |
| **Sorbitol** (UNII: 506T60A25R) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | PURPLE | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | GRAPE | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:45014-153-04 | 118 mL in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part341 | 11/04/2009 | |

## Labeler - Accudial Pharmaceutical, Inc. (831999201)

Revised: 11/2009 Accudial Pharmaceutical, Inc.