

DAYTIME COUGH AND COLD- 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.

Drug Facts

Active ingredients (in each 5 mL, 1 teaspoonful)	Purposes
Dextromethorphan HBr, USP 5 mg	Cough suppressant
Phenylephrine HCl, USP 1.25 mg	Nasal decongestant

Uses

- temporarily relieves
 - nasal and sinus congestion
 - cough due to minor throat and bronchial irritation 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.

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts, or as occurs with asthma

When using this product

- **do not exceed recommended dosage**

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days or occur with a fever
- cough persists for more than 7 days, comes back, or occurs with a fever, rash, or persistent headache. 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 6 hours. Do not give more than 4 doses in 24 hours unless directed by a doctor.
-

Children under 4 years of age	do not use
Children 4 to under 6 years of age	1-1½ tsp. (5-7.5 mL)
Children 6 to under 12 years of age	1½-3 tsp. (7.5-15 mL)

Other information

- **each teaspoon contains:** sodium 2 mg
- store at controlled room temperature 20°-25°C (68°-77°F)

Inactive ingredients

Artificial Flavor, Benzoic Acid, Citric Acid, EDTA Disodium, FD&C Red #40, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol.

📞 877-434-2036

Manufactured for
**ACCUDIAL
PHARMACEUTICAL, INC.**
AccurateDose.com
Palm Beach Gardens, FL 33410

Distributed by:
LeSaint Logistics
Corporate Headquarters
2570 Northwest Parkway
Elgin, IL 60124

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

**CHILDREN'S
ACCUDIAL**

ROTATING DOSING LABEL

**Daytime
Cough & Cold**

**ACCURATE DOSING
BY WEIGHT**

Dextromethorphan HBr
(Cough Suppressant)

Phenylephrine HCl
(Nasal Decongestant)

**Cough
Stuffy Nose**

For Ages 4 to under 12

*Compares to the active
ingredients in Children's
Triaminic® Day Time
Cold & Cough.*

CHERRY

FLAVOR

4 FL.OZ.

(118 mL)

NDC 45014-152-04



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ACCUDIAL**



DAYTIME COUGH & COLD

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Drug Facts (continued)

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LOT

EXP:

DAYTIME COUGH AND COLD

dextromethorphan hydrobromide and phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45014-152
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
Cherry (UNII: BUC5I9595W)	
Benzoic acid (UNII: 8SKN0B0MIM)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Edetate Disodium (UNII: 7FLD91C86K)	
FD&C red no. 40 (UNII: WZB9127XOA)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Sodium Citrate (UNII: 1Q73Q2JULR)	

Saccharin Sodium (UNII: SB8ZUX40TY)	
Sorbitol (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45014-152-04	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/26/2009	

Labeler - Accudial Pharmaceutical, Inc. (831999201)

Revised: 9/2011

Accudial Pharmaceutical, Inc.