

# **DAYTIME COUGH AND COLD- dextromethorphan hydrobromide and phenylephrine hydrochloride solution**

**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.*

-----

## **Daytime Cough & Cold**

### ***Drug Facts***

<b><i>Active ingredient (in each 5 mL = 1 teaspoon)</i></b>	<b><i>Purpose</i></b>
Dextromethorphan HBr, USP 5 mg	Cough suppressant
Phenylephrine HCl, USP 2.5 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.

Consult your pharmacist or health care provider for any appropriate, additional dosage delivery device necessary for use when a physician recommends a dose that is different than the doses that appear on the dosage delivery device that accompanies this product.

<b>Age (yr)</b>	<b>Dose (TSP)</b>
under 4 yrs.	ask a doctor
4 to under 6	1 TSP

6 to under 12	2 TSP
or as directed by a doctor	

TSP = teaspoon

Keep out of reach of children.

### **Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Prompt medical attention is critical, even if you do not notice any signs or symptoms.

### **Other information**

- **each teaspoon contains: sodium 2 mg**
- store between 20°-25°C (68°-77°F)
- **tamper evident:** do not use if foil seal over the mouth of the bottle is torn, broken, or missing.

### **Directions**

- may be given every 4 hours
- do not use more than 6 times in 24 hours
- use only enclosed dosing cup to dose this product. Do not use any other dosing device.

### **Questions?**

**877-434-2036**

### **Inactive ingredients**

artificial flavor, benzoic acid, citric acid, EDTA disodium dihydrate, FD&C red #40, propylene glycol, purified water, sodium citrate, sodium saccharin, sorbitol.

Distributed by: AccuDial® Pharmaceutical, Inc.  
Palm Beach Gardens, FL 33408

### **PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label**

**ACCUDIAL®**

**Children's  
Daytime  
Cough and Cold**

**Dextromethorphan HBr (Cough Suppressant)**

**Phenylephrine HCl (Nasal Decongestant)**

**Relieves Cough • Stuffy Nose**

***Earth-Friendly  
Package!***

For Ages 4 yrs to under 12 yrs

**Tamper Evident**

Compares to Children's Triaminic®  
Day Time Cold & Cough

**CHERRY  
FLAVOR**

NDC 45014-158-04  
4 FL. OZ. (118 mL)

▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶ TURN LABEL FOR DRUG FACTS ▶▶▶

**Drug Facts**

**Active ingredient**  
(in each 5 mL = 1 teaspoon)      **Purpose**

Dextromethorphan  
HBr, USP 5 mg.....Cough suppressant  
Phenylephrine HCl,  
USP 2.5 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. →

**ACCUDIAL®**  
**Children's Daytime Cough and Cold**

Dextromethorphan HBr (Cough Suppressant)  
Phenylephrine HCl (Nasal Decongestant)

**Relieves Cough • Stuffy Nose**

Earth-Friendly Package!  
Tempor Efficacy

For Ages 4 yrs to under 12 yrs  
Compares to Children's Triaminic® Day Time Cold & Cough

CHERRY FLAVOR

NDC 45014-158-04  
4 FL. OZ. (118 mL)

**Drug Facts (continued)**

**Other information**

- each teaspoon contains: sodium 2 mg
- store between 20°-25°C (68°-77°F)
- **tamper evident:** do not use if foil seal over the mouth of the bottle is torn, broken, or missing.

**Directions**

- may be given every 4 hours
- do not use more than 6 times in 24 hours
- use only enclosed dosing cup to dose this product. Do not use any other dosing device.

3 45014 00061 6

**Questions? 877-434-2036**

Distributed by: AccuDial® Pharmaceutical, Inc.  
Palm Beach Gardens, FL 33408

U.S. Patent Nos. 6,276,533 and 7,172,668.

**Drug Facts (continued)**

**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.

**Drug Facts (continued)**

**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.

**Drug Facts (continued)**

Consult your pharmacist or health care provider for any appropriate, additional dosage delivery device necessary for use when a physician recommends a dose that is different than the doses that appear on the dosage delivery device that accompanies this product.

Age (yr)	Dose (TSP)
under 4 yrs.	ask a doctor
4 to under 6	1 TSP
6 to under 12	2 TSP
or as directed by a doctor	

TSP = teaspoon

**Drug Facts (continued)**

Keep out of reach of children.  
Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In the case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Prompt medical attention is critical, even if you do not notice any signs or symptoms.

6 yrs to under 12 yrs → 2 TSP

4 yrs to under 6 yrs → 1 TSP

under 4 yrs → Ask a Doctor

5345-0712 201  
Go Green Daytime Cough & Cold

<b>DAYTIME COUGH AND COLD</b>			
dextromethorphan hydrobromide and phenylephrine hydrochloride solution			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:450 14-158
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3R0TS)	Dextromethorphan Hydrobromide	5 mg in 5 mL	
<b>Phenylephrine Hydrochloride</b> (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg in 5 mL	

## Inactive Ingredients

Ingredient Name	Strength
<b>Benzoic Acid</b> (UNII: 8SKN0B0MIM)	
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
<b>Edetate Disodium</b> (UNII: 7FLD91C86K)	
<b>FD&amp;C Red No. 40</b> (UNII: WZB9127XOA)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Water</b> (UNII: 059QF0K00R)	
<b>Sodium Citrate</b> (UNII: 1Q73Q2JULR)	
<b>Saccharin Sodium</b> (UNII: SB8ZUX40TY)	
<b>Sorbitol</b> (UNII: 506T60A25R)	

## Product Characteristics

<b>Color</b>	RED	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45014-158-04	118 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/01/2013	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Bio-Pharm, Inc.		801652546	ANALYSIS(45014-158) , MANUFACTURE(45014-158) , RELABEL(45014-158) , REPACK(45014-158)

Revised: 2/2013

Accudial Pharmaceutical, Inc.