TRIACTING DAYTIME COLD COUGH CHILDRENS- dextromethorphan hbr, phenylephrine hcl liquid

Walgreens

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)

Dextromethorphan HBr 5 mg Phenylephrine HCl 2.5 mg

Purposes

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves:
 - nasal and sinus congestion
 - o 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
- a breathing problem such as chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts, or as occurs with asthma.

When using this product,

do not use more than directed.

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 (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL = milliliter
- shake well before using

age	dose
children 6 to under 12 years of age	10 mL every 4 hours
children 4 to 5 years	5 mL every 4 hours
children under 4 years	do not use

Other information

- each 5 mL contains: sodium 2 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

acesulfame potassium, alcohol, benzoic acid, citric acid, disodium EDTA, FD&C red #40, maltitol, flavor, propylene glycol, purified water, sodium citrate

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Children's Daytime

Cold & Cough

Dextromethorphan HBr / Cough suppressant

Phenylephrine HCl / Nasal decongestant

• Alcohol 0.14%

Cherry Flavor

FL OZ (mL)

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200 WILMOT RD., DEERFIELD, IL 60015

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TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

Package Label

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W10040-XXXX-F ITEM 448737 PLD-F319C LB003474 REV1013-RF_R01



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Well at Walgreens Childrens Daytime Cold & Cough Cherry Liquid

TRIACTING DAYTIME COLD COUGH CHILDRENS

dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-3780
Route of Administration	ORAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength DEXTROMETHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) DEXTROMETHORPHAN 5 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) **HYDROBROMIDE** in 5 mL PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 2.5 mg UNII:1WS297W6MV) HYDROCHLORIDE in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230 V73Q5G9)		
ALCOHOL (UNII: 3K9958V90M)		
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
MALTITOL (UNII: D65DG142WK)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-3780- 04	1 in 1 BOX	07/31/2015	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/31/2015	

Labeler - Walgreens (008965063)

Revised: 6/2016 Walgreens