CHILDRENS PLUS MULTI SYMPTOM COLD DYE FREE- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)

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)

Acetaminophen 160 mg

Chlorpheniramine maleate 1 mg

Dextromethorphan HBr 5 mg

Phenylephrine HCl 2.5 mg

Purpose

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves the following cold/flu symptoms:
 - minor aches and pains
 - sore throat
 - cough
 - sneezing and runny nose
 - headache
 - o nasal congestion
 - stuffy nose
- temporarily reduces fever

Warnings

Liver warning: This product contain acetaminophen. Severe liver damage may occur if your child take:

- more than 5 doses (10 mL) in 24 hours, which is the maximum daily amount.
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- to make a child sleepy
- wth any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if the child has

- liver disease
- glaucoma
- thyroid disease
- diabetes
- heart disease
- high blood pressure
- a breathing problem such as chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

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

- sedatives or tranquilizers
- the blood thinning drug warfarin

When using this product

- do not exceed recommended dose (see overdose warning)
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain, nasal congestion or cough gets worse or last more than 5 days
- fever gets worse or last more than 3 days
- nervousness, dizziness or sleeplessness occurs
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

Keep out of reach of children.

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

Directions

- this product does not contain directions or complete warnings for adult use
- mL=milliliter
- shake well before using

- do not give more than 5 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- if needed, repeat dose every 4 hours while symptoms last
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age

Weight (lb)	Age (yr)	Dose (mL)
48-95 6-11 10 mL		10 mL
36-47	4-5	do not use unless directed by a doctor
under 36	under 4	do not use

Other information

• store at 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium,flavor, glycerin, microcrystalline cellulose, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum

Questions or comments?

Call toll free 1-866-4-REXALL

Principal Display Panel

Children's Plus Multi-Symptom Cold

ORAL SUSPENSION

Relief of

- Fever & sore throat **ACETAMINOPHEN**
- Sneezing & runny nose CHLORPHENIRAMINE MALEATE
- Cough **DEXTROMETHORPHAN HBr**
- Stuffy nose **PHENYLEPHRINE HCI**

FOR AGES 6-11 YEARS

DYE Free

Grape Flavor

Dosing Cup Included

FL OZ (mL)

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

PACKAGED FOR DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072 USA

Visit us at: Rexall.com

Package Label



REXALL Children's Plus Multi-Symptom Cold Dye Free Grape Flavor

CHILDRENS PLUS MULTI SYMPTOM COLD DYE FREE

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:5591	10-303
Route of Administration	ORAL				
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Active Ingredient/Active Moiety					
Ingredient Name		Basis of Str	ength	Strength	
					100

ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	in 5 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCROSE (UNII: C151H8 M554)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

ı	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:55910-303- 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 - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)