# CHILDRENS PLUS MULTI SYMPTOM COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension 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.

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## **Drug Facts**

# Active ingredients (in each 5 mL)

## Acetaminophen 160 mg

Chlorpheniramine maleate 1 mg
Dextromethorphan HBr 5 mg
Phenylephrine HCl 2.5 mg

### **Purposes**

#### Pain reliever/fever reducer

**Antihistamine** 

Cough suppressant

Nasal decongestant

#### Uses

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

#### Warnings

**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.

**Liver warning**: This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs contaning acetaminophen

**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
- with 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product

## Ask a doctor before use if your child has

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

## Ask a doctor or pharmacist before use if your 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
- fever gets worse or lasts for more than 3 days
- redness or swelling is present

- pain, nasal congestion or cough gets worse or lasts for more than 5 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) immediately. Quick medical attention is critical 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
- measure only with dosing cup provided
- do not use any other dosing device
- keep dosing cup with product
- do not give more than 5 times in 24 hours
- 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)		Dose (mL)
48-95	6-11	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**

carboxymethylcellulose sodium, citric acid, D&C red #33, FD&C blue #1, FD&C red #40, flavor, glycerin, microcrystalline cellulose, purified water, sodium benzoate, sorbitol, sucrose, xanthan gum

#### Questions or comments?

Call 1-888-309-9030

## **Principal Display Panel**

Ages 6 to 11 years

## Children's Plus Multi-Symptom Cold

## Acetaminophen

Chlorpheniramine Maleate

Dextromethorphan HBr

Phenylephrine HCI

**Oral Suspension** 

Pain reliever/fever reducer

**Antihistamine** 

Cough suppressant

Nasal decongestant

\*Compare to active ingredients in Children's Tylenol® Plus Multi-Symptom Cold

Grape Flavored

Relieves:

Fever

Sore Throat

Sneezing

Runny Nose

Cough

Stuffy Nose

FL OZ (mL)

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DISTRIBUTED BY DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

## Package Label



Dollar General Children's Plus Multi Symptom Cold Suspension

#### CHILDRENS PLUS MULTI SYMPTOM COLD

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-043
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	160 mg in 5 mL	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE	2.5 mg	

UNII:1WS297W6MV) HYDROCHLORIDE in 5 mL

Inactive Ingredients			
Ingredient Name	Strength		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SORBITOL (UNII: 506T60A25R)			
SUCROSE (UNII: C151H8M554)			
XANTHAN GUM (UNII: TTV12P4NEE)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55910- 043-04	1 in 1 BOX	04/30/2015	04/30/2025	
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	04/30/2015	04/30/2025

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

Revised: 1/2023 Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)