CHILDRENS PLUS MULTI SYMPTOM COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension Care One (American Sales Company)

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
 - nasal congestion
 - stuffy nose
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occurif your child takes:

- 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
- 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.
- with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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) right away. Quick medical attention is critical for adultsas 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
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- do not give more than 5 doses in any 24-hours period
- 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	
36-47 4-5		do not use unless directed by a doctor	
under 36	under 4	do not use	

Other Information

- store between 20-25°C (68-77°F)
- do not refrigerate.

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, 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 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

For Ages 6-11 Years

Children's Multi-Symptom Cold

Pain Relief / Fever Reducer - ACETAMINOPHEN, 160 mg Antihistamine - Chlorpheniramine Maleate, 1 mg Cough Suppressant - Dextromethorphan HBr, 5 mg Nasal Decongestant - Phenylephrine HCI, 2.5 mg

FOR RELIEF OF:

- Fever & Sore Throat
- Sneezing and Runny Nose
- Cough
- Stuffy Nose

Oral Suspension

Dosage Cup Provided

Grape Flavored

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

DISTRIBUTED BY:

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

1-877-846-9949

Package Label



CHILDRENS PLUS MULTI SYMPTOM COLD

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension

PLD-I253C FC004119

Lot No.: Exp. Date

CAREONE Childrens Multi-Symptom Cold Grape Flavor

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:41520-704	
Route of Administration	ORAL				
A ative laws diamt/A ative					
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: V1Q0O9OJ9Z) (CHLOR	PHENIRAMINE -	CHLORPHENIRAMI	NE	1 mg

I	UNII:3U6IO1965U)	MALEATE	in 5 mL
	DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
	PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg 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: WZ B9127XOA)			
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			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41520- 704-04	1 in 1 BOX	10/31/2015		
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	

Labeler - Care One (American Sales Company) (809183973)