

CHILDRENS PLUS COUGH AND RUNNY NOSE- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide suspension
Care One (American Sales Company)

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

Purposes

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Uses

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

Warnings

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 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 the child has

- liver disease
- glaucoma
- 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
- fever gets worse or lasts for more than 3 days
- redness or swelling is present
- pain or cough gets worse or lasts for more than 5 days
- 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 even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use.**
- do not take 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
- mL=milliliter
- shake well before using
- 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
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Other Information

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

Inactive ingredients

acesulfame potassium, alcohol, carboxymethylcellulose sodium, citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?

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

Principal Display Panel

Children's Plus Cough & Runny Nose

Acetaminophen / Pain Reliever / Fever Reducer

Chlorpheniramine maleate / Antihistamine

Dextromethorphan HBr / Cough Suppressant

Cherry Flavor

Alcohol 0.02%

Oral suspension

Temporarily relieves:

- fever
- cough
- sore throat
- sneezing
- runny nose

FL OZ (mL)

Dosage Cup Provided

For ages 6 to 11

DISTRIBUTED BY

FOODHOLD USA LC

LANDOVER, MD 20785

1-877-846-9949

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

Package Label

NO TAMPERING COATING

Drug Facts (continued)

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Inactive ingredients acacia, caffeine potassium, alcohol, carbonated water, citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose, purified water, sodium benzoate, sorbitol, xanthan gum

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PARENTS:
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NDC 41520-297-04

CAREONE®

CHILDREN'S PLUS

PAIN RELIEVER/
FEVER REDUCER
ANTIHISTAMINE
COUGH SUPPRESSANT

COUGH AND RUNNY NOSE

Acetaminophen
Chlorpheniramine Maleate
Dextromethorphan HBr

CHERRY FLAVOR Oral Suspension

Alcohol 0.02%

Temporarily Relieves:

- Fever
- Cough
- Sore Throat
- Sneezing
- Runny Nose

For Ages 6 to 11

4 FL OZ (118 mL)

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Care One Childrens Plus Cough and Runny Nose Cherry Oral Suspension

CHILDRENS PLUS COUGH AND RUNNY NOSE			
acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-297
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	160 mg in 5 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)		CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
Inactive Ingredients			

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-297-04	1 in 1 BOX	09/30/2015	12/31/2020
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	09/30/2015	12/31/2020

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

Revised: 10/2019

Care One (American Sales Company)