

**CAREONE CHILDRENS COLD AND FLU- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl suspension**  
**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.*

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**American Sales Company Children's Cold & Flu 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
- headache
- sore throat
- cough
- stuffy nose
- 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**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- if your child has ever had an allergic reaction to this product or any of its ingredients

### **Ask a doctor before use if your child has**

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

### **Ask a doctor or pharmacist before use if your child is**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

### **When using this product**

- **do not exceed recommended dosage (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**

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

- 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:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 give more than directed (see overdose warning)**
- **shake well before using**
- mL = milliliter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child’s dose into the dosing cup
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL)*</b>
under 36	under 4 years	do not use
36-47	4 to 5 years	do not use unless directed by a doctor
48-95	6 to 11 years	10 mL

\* or as directed by a doctor

**Attention:** use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

**Other information**

- **each 5 mL contains:** sodium 3 mg
- store at 20-25°C (68-77°F).
- do not use if printed neckband is broken or missing

**Inactive ingredients**

anhydrous citric acid, calcium sulfate, carrageenan, D&C red #33, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, tribasic sodium phosphate, xanthan gum

**Questions or comments?**

1-800-719-9260

**Package/Label Principal Display Panel**

Compare to the active ingredients in Children’s Tylenol® Cold + Flu Oral Suspension

For Ages 6 to 11

Children's

COLD & FLU

Pain Reliever/Fever Reducer-Acetaminophen

Antihistamine-Chlorpheniramine Maleate

Cough Suppressant-Dextromethorphan HBr

Nasal Decongestant-Phenylephrine HCl

Oral Suspension

RELIEF OF:

Fever • Sore Throat

Sneezing • Runny Nose

Cough • Stuffy Nose

OUR PHARMACISTS RECOMMEND

Grape Flavor

4 FL OZ (118mL)



## CAREONE CHILDRENS COLD AND FLU

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl suspension

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-833
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CALCIUM SULFATE (UNII: WAT0DDB505)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
SODIUM PHOSPHATE, TRIBASIC (UNII: A752Q30A6X)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-833-26	1 in 1 CARTON	08/01/2018	
1		118 mL in 1 BOTTLE; 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	08/01/2018	

**Labeler** - American Sales Company (809183973)

