# CHILDRENS PLUS MULTI SYMPTOM COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension Best Choice (Valu Merchandisers 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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# **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
  - sore throat
  - cough
  - sneezing and runny nose
  - headache
  - nasal congestion
  - stuffy nose
- temporarily reduces fever

# **Warnings**

**Liver warning**: This product contains acetaminophen. Severe liver damage may occur if 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 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 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
- redness or swelling is present
- pain, nasal congestion or cough gets worse or lasts 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 adult 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-hours peroid
- 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		
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

COMPARE TO THE ACTIVE INGREDIENTS IN CHILDREN'S TYLENOL® PLUS MULTI-SYMPTOM COLD\*

# Children's Plus Multi-Symptom Cold

## Acetaminophen

• Pain Reliever / Fever Reducer

## Chlorpheniramine Maleate

Antihistamine

## Dextromethorphan HBr

Cough Suppressant

## Phenylephrine HCl

• Nasal Decongestant

## Grape Flavor

**Oral Suspension** 

FL OZ (mL)

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Plus Multi-Symptom Cold.

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.

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

5000 KANSAS AVE

KANSAS CITY, KS 66106

www.bestchoicebrand.com

# **Package Label**



**BEST CHOICE Children's Plus Multi-Symptom Cold** 

PLD-H253C FC004114

Lot No.: Exp. Date:

## CHILDRENS PLUS MULTI SYMPTOM COLD

suspension

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-304	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	160 mg in 5 mL	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL	

Inactive Ingredients	
Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
ANHYDRO US 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:63941-304- 04	1 in 1 BOX	05/31/2015		
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	05/31/2015		

Labeler - Best Choice (Valu Merchandisers Company) (868703513)

Revised: 3/2018 Best Choice (Valu Merchandisers Company)