# CHILDRENS PLUS MULTI SYMPTOM COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid Family Dollar (FAMILY WELLNESS)

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

#### **Purpose**

#### 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

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

- 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
- 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- 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 phleam (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 ocur
- 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 lasts 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 even if you do not notic 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-hour period
- 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

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

#### **Questions or comments?**

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

#### **Principal Display Panel**

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

#### Children's

### Pain Relief + Multi-Symptom Cold

#### Acetaminophen,

Pain Reliever/Fever Reducer

Chlorpheniramine Maleate, Antihistamine

Dextromethorphan HBr, Cough Suppressant

Phenylephrine HCL, Nasal Decongestant

For Ages 6-11 Years

#### Relieves

- Fever
- Sore Throat
- Runny Nose
- Sneezing
- Cough
- Stuffy Nose
- Nasal Congestion

**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-Symtpom Cold.

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: MIDWOOD BRANDS, LLC** 

**500 VOLVO PARKWAY, CHESAPEAKE, VA 23320** 

Package Label



his product is not manufactured or distributed by McNeii Conseathcare, distributor of Children's Tylenot<sup>a</sup> Plus Multi-Symptor

DISTRIBUTED BY: MIDWOOD BRANDS, LLC 500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

NOT 100% SATISFIED? Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

PARENTS:

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



COMPARE TO THE ACTIVE INGREDIENTS IN ILDREN'S TYLENOL® PLUS MULTI-SYMPTOM COLD®

FAMILY ■ Wellness™

## Pain Reliever/Fever Reducer

Chlorpheniramine Maleate, Antihistamine Dextromethorphan HBr, Cough Suppressant Phenylephrine HCl, Nasal Decongestant

#### For Ages 6-11 Years



Oral Suspension

4 fl oz (118 mL)



COMPARE TO THE ACTIVE INGREDIENTS IN HILDREN'S TYLENOL® PLUS MULTI-SYMPTOM COLD

FAMILY ■ Wellness™

NDC 55319-304-04

#### Children's Pain Relief + Multi-Symptom Cold

#### Acetaminophen,

Pain Reliever/Fever Reducer Chlorpheniramine Maleate, Antihistamine Dextromethorphan HBr, Cough Suppressant Phenylephrine HCl, Nasal Decongestant

#### For Ages 6-11 Years

Relieves

Fever

Sore Throat

Runny Nose

Stuffy Nose

Oral Suspension

Nasal Congestion

4 fl oz (118 mL)

Sneezing

Cough



Drug Facts Active ingredients (in each 5 mL) Purposes Chloroheniramine maleate 1 mg. Antihistam Dextromethorphan HBr 5 mg... Phenylephrine HCl 2.5 mg..... ..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 temporarily reduces fever stuffy nose

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FAMILY WELLNESS Children's Pain Relief plus Multi-Symptom Cold

#### CHILDRENS PLUS MULTI SYMPTOM COLD

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

#### **Product Information Product Type HUMAN OTC DRUG Item Code (Source)** NDC:55319-304 **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	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	5 mg	

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 5 mL
,	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: 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			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:55319- 304-04	1 in 1 BOX	11/30/2014	11/30/2024	
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	11/30/2014	11/30/2024	

## Labeler - Family Dollar (FAMILY WELLNESS) (024472631)