# CHILDRENS PLUS MULTI SYMPTOM COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension Walgreens

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
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

# 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 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 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-hour 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**

Compare to the active ingredients in Children's Tylenol® Plus Multi-Symptom Cold††

Multi-Symptom

Children's

#### Cold + Flu

ACETAMINOPHEN /

PAIN RELIEVER / FEVER REDUCER

CHLORPHENIRAMINE MALEATE /

**ANTIHISTAMINE** 

DEXTROMETHORPHAN HBr /

**COUGH SUPPRESSANT** 

PHENYLEPHRINE HCI /

#### NASAL DECONGESTANT

- Relieves aches, fever, sore throat, sneezing, cough, runny & stuffy nose
- Oral suspension

AGES 6 -11 YEARS

FL OZ (mL)

Grape flavor

DOSAGE CUP PROVIDED

††This product is not manufactured or distributed bt McNeil Consumer Healthcare, distributor of Children's Tylenol® Plus Multi-Symptom 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: WALGREEN CO

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

# Package Label



WALGREENS Multi-Symptom Children's Cold and Flu

Lot No.:

#### CHILDRENS PLUS MULTI SYMPTOM COLD

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0034
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	

<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (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: 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			

F	Packaging					
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0363- 0034-04	1 in 1 BOX	04/30/2015			
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	04/30/2015	

# Labeler - Walgreens (008965063)

Revised: 3/2022 Walgreens