

PAIN RELIEF PLUS MULTI SYMPTOM COLD CHILDRENS- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid P & L Development, LLC

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
 - 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 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 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
- 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 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 ingredient in **Children's Tylenol® Plus Multi-Symptom Cold***

Children's

pain relief plus multi-symptom cold

Acetaminophen 160 mg

Chlorpheniramine Maleate 1 mg

Dextromethorphan HBr 5 mg

Phenylephrine HCl 2.5 mg

for ages 6-11 years

oral suspension

Relieves:

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

grape flavor

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 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

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Package Label

Drug Facts (continued)

- nervousness, dizziness or sleeplessness occurs
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

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Inactive ingredients carboxymethylcellulose sodium, citric acid, 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?
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PARENTS:
Learn about the medicine online
www.StopMedicineAbuse.org



Manufactured by:
PL Developments
11865 S. Alameda St
Lynwood, CA 90262



Compare to the active ingredients in
Children's Tylenol® Plus Multi-Symptom Cold*
NDC 49580-0304-4

children's
pain relief plus
multi-symptom
cold

Acetaminophen 160 mg
chlorpheniramine maleate 1 mg
dextromethorphan HBr 5 mg
phenylephrine HCl 2.5 mg



for ages 6-11 years
oral suspension

relieves:

- fever
- sore throat
- runny nose
- sneezing
- cough
- stuffy nose
- nasal congestion



4 fl oz (118 mL)

grape flavor



Compare to the active ingredients in
Children's Tylenol® Plus Multi-Symptom Cold*
NDC 49580-0304-4

children's
pain relief plus
multi-symptom
cold

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- fever gets worse or lasts more than 3 days



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PLD-A263C FC007674

Lot No.:

Exp. Date:

READYinCASE Children's Pain Relief Multi-Symptom Cold

PAIN RELIEF PLUS MULTI SYMPTOM COLD CHILDRENS

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0304
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: 9D2RT19KYH)	DEXTROMETHORPHAN	5 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
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
1	NDC:49580-0304-4	1 in 1 BOX	03/26/2021	01/26/2026
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 Drug	M012	03/26/2021	01/26/2026

Labeler - P & L Development, LLC (101896231)