

CHILDRENS PLUS COLD- acetaminophen, chlorpheniramine maleate, phenylephrine hci 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.

Drug Facts

Active ingredients (in each 5 mL)

Acetaminophen 160 mg

Chlorpheniramine maleate 1 mg

Phenylephrine HCl 2.5 mg

Purposes

Pain reliever/fever reducer

Antihistamine

Nasal decongestant

Uses

- temporarily relieves the following cold/flu symptoms:
 - minor aches and pains
 - headache □
 - nasal congestion □□
 - sneezing and runny nose
 - sore throat
 - stuffy nose
- temporarily reduces fever

Warnings

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

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

- more than 5 doses (10 mL each) in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

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 drug containing acetaminophen (prescription or non prescription). 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving 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
- diabetes
- glaucoma
- thyroid disease
- heart disease
- high blood pressure
- a breathing problem such as chronic bronchitis

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 or nasal congestion gets worse or lasts more than 5 days
- fever gets worse or last more than 3 days
- nervousness, dizziness or sleeplessness occurs

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(68-77F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, D&C red #33, FD&C blue #1, FD&C red 40, flavors, glycerin, microrocrystalline 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

children's plus

Cold

Acetaminophen / Pain reliever / fever reducer

Chlorpheniramine maleate / Antihistamine

Phenylephrine HCl / Nasal Decongestant

Relieves:

- Fever & sore throat
- Sneezing & runny nose
- Stuffy nose
- Oral suspension
- For ages 6 to 11 years

Grape Flavor

DOSAGE CUP PROVIDED

FL OZ (mL)

Compare to Children's Tylenol® Plus Cold active ingredient≠≠

≠≠This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Plus 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

DISTRIBUTED BY: WALGREEN CO

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

Package Label

Drug Facts (continued)

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 adults as well as children even if you do not notice any signs or symptoms.

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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

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*Walgreens Pharmacist Survey Study, November 2010.
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DISTRIBUTED BY: WALGREEN CO.
 200 WILMOT RD., DEERFIELD, IL 60015
 100% SATISFACTION GUARANTEED
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DOSAGE CUP PROVIDED

PLD-G245D FC003225

ITEM 510119 W10067-XXXX-L



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WALGREENS PHARMACIST RECOMMENDED*

children's plus Cold

**Acetaminophen /
 Fever Reducer / Pain Reliever
 Chlorpheniramine Maleate /
 Antihistamine
 Phenylephrine HCl /
 Nasal Decongestant**

Relieves:

- Fever & sore throat
- Sneezing & runny nose
- Stuffy nose
- Oral suspension
- For ages 6 to 11 years



4 FL OZ (118 mL) GRAPE FLAVOR

Compare to Children's Tylenol® Plus Cold active ingredients**

NDC 0363-0026-04



WALGREENS PHARMACIST RECOMMENDED*

children's plus Cold

**Acetaminophen /
 Fever Reducer / Pain Reliever
 Chlorpheniramine Maleate /
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Well at Walgreens Children's Plus Cold Grape Liquid

CHILDRENS PLUS COLD

acetaminophen, chlorpheniramine maleate, phenylephrine hci suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0026
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0026-04	1 in 1 BOX	03/31/2015	12/31/2020
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	03/31/2015	12/31/2020

Labeler - Walgreens (008965063)

Revised: 12/2018

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