

CHILDRENS PLUS MULTI SYMPTOM COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension
Freds Inc

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 contain 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 for 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

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

6-11 YEARS

CHILDREN'S PAIN RELIEF

+ MULTI-SYMPTOM COLD

Acetaminophen 160 mg Pain Reliever / Fever Reducer

CHLORPHENIRAMINE MALEATE 1 mg Antihistamine

DEXTROMETHORPHAN HBr 5 mg Cough Suppressant

PHENYLEPHRINE HCl 2.5 mg Nasal Decongestant

Relieves:

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

GRAPE FLAVOR

Oral Suspension

FL OZ (mL)

*Compare To Active Ingredients in Children's Tylenol® Plus Multi-Symptom Cold

*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

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

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.

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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PARENTS: Learn about teen medicine abuse
www.StopMedicineAbuse.org

100% satisfaction guaranteed

Questions or comments:
1-855-331-FRED (3733)

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD, MEMPHIS, TN 38118
www.fredsinc.com

fred's Pharmacy NDC 55315-304-04

6-11 YEARS

CHILDREN'S PAIN RELIEF + MULTI-SYMPOM COLD

ACETAMINOPHEN 160mg
Pain Reliever/Fever Reducer
CHLORPHENIRAMINE MALEATE 1mg
Antihistamine
DEXTROMETHORPHAN HBr 5mg
Cough Suppressant
PHENYLEPHRINE HCl 2.5mg
Nasal Decongestant

Relieves:

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

GRAPE FLAVOR
Oral Suspension

4 FL OZ (118 mL)

*Compare To Active Ingredients in Children's Tylenol® Plus Multi-Symptom Cold

fred's Pharmacy NDC 55315-304-04

6-11 YEARS

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- redness or swelling is present
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- fever gets worse or lasts more than 3 days



Lot No.:
Exp. Date:

FRED'S PHARMACY Children's Pain Relief + multi-Symptom Cold

CHILDRENS PLUS MULTI SYMPTOM COLD			
acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-304
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: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg 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:55315-304-04	1 in 1 BOX	03/31/2015	06/30/2024
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 Drug	M012	03/31/2015	06/30/2024

Labeler - Freds Inc (005866116)