

**COUGH AND RUNNY NOSE CHILDRENS PLUS- acetaminophen,
chlorpheniramine maleate, dextromethorphan hydrobromide suspension
TOP CARE (Topco Associates LLC)**

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

Dextromethorphan HBr 5 mg

Purposes

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Uses

- temporarily relieves the following cold/flu symptoms:
 - minor aches and pains
 - sore throat
 - cough
 - sneezing and runny nose
 - headache
- 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 each) 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
- 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 or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- 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 adult as well as

children 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

acesulfame potassium, alcohol, carboxymethylcellulose sodium, citric acid, D&C red #33, FD&C red #40, flavors, glycerin, high fructose corn syrup, microcrystalline cellulose purified water, sodium benzoate, sorbitol, xanthan gum

Questions or comments?

Call toll free 1-888-425-0139

Principal Display Panel

COMPARE TO CHILDREN'S TYLENOL® PLUS COUGH & RUNNY NOSE ACTIVE INGREDIENTS*

Children's

Pain Relief Plus

Cough & Runny Nose

ORAL SUSPENSION

ACETAMINOPHEN 160 mg PAIN RELIEVER • FEVER REDUCER

CHLORPHENIRAMINE MALEATE 1 mg ANTIHISTAMINE

DEXTROMETHORPHAN HBr 5 mg COUGH SUPPRESSANT

RELIEVES:

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

Ages 6 to 11 Years

CHERRY FLAVOR

Alcohol 0.005%

FL OZ (mL)

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Tylenol® Plus Cough & Runny Nose.

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 TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

www.topcarebrand.com

Package Label

Drug Facts (continued)

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 ELK GROVE VILLAGE, IL 60007
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 QUESTIONS? 1-888-423-0139
 topcare@topco.com www.topcarebrand.com

PARENTS:
 Learn about our medicine online
 www.StopMedicineAbuse.org



✓ QUALITY GUARANTEED

Scan here for more information or call 1-888-423-0139

NDC 36800-297-04



COMPARE TO CHILDREN'S TYLENOL® PLUS COUGH & RUNNY NOSE ACTIVE INGREDIENTS*

children's Pain Relief Plus Cough & Runny Nose

ORAL SUSPENSION

ACETAMINOPHEN 160 mg
 PAIN RELIEVER • FEVER REDUCER

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 COUGH SUPPRESSANT

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4 FL OZ (118 mL) Alcohol 0.005%

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PLD-K246D FC004531

Lot No.:

Exp. Date:

TOPCARE HEALTH Children's Pain Relief Plus Cough & Runny Nose

COUGH AND RUNNY NOSE CHILDRENS PLUS

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-297
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	5 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)

HYDROBROMIDE

in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
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)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-297-04	1 in 1 BOX	12/31/2015	
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	12/31/2015	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 12/2022

TOP CARE (Topco Associates LLC)