TOPCARE COLD- acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl suspension 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.

Topco Associates LLC. Children's Pain Relief Plus Multi-Symptom Cold 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
- minor aches and pains
- headache
- minor sore throat pain
- runny nose
- itchy nose or throat
- sneezing
- itchy, watery eyes due to hay fever
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily reduces fever

Warnings

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

- more than 5 doses 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

- in a child under 4 years of age
- if your child has ever had an allergic reaction to this product or any of its ingredients
- 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.
- to make a child sleepy

Ask a doctor before use if your child has

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 your child is taking

- sedatives or tranquilizers
- blood thinning drug warfarin

When using this product

- do not exceed recommended dosage
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- new symptoms occur
- 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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
- do not give more than directed (see Overdose warning)
- shake well before using
- remove the child protective cap and squeeze your child's dose into the dosing cup
- may be given every 4 hours, while symptoms persist. Do not give more than 5 doses in 24 hours unless directed by a doctor.
- use enclosed dosing cup only. Keep for use with this product. Do not use any other dosing device.

Age	Dose	
children under 4	do not use	
years of age		
children 4 to under 6	do not use unless directed by a doctor	
years of age		
children 6 to under 12 years of age	10 mL	

Other information

- each 5 mL contains: sodium 3 mg
- contains no aspirin
- store at 20-25°C (68-77°F). Protect from light.
- close cap tightly

Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, D&C red #33, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, polysorbate 80, purified water, sodium benzoate, sorbitol solution, sucrose, tribasic sodium phosphate, xanthan gum

Questions or comments?

1-888-423-0139

Principal Display Panel

COMPARE TO CHILDREN'S TRIAMINIC® MULTI-SYMPTOM FEVER & COLD ACTIVE INGREDIENTS
TRIACTING SUSPENSION

children's Pain Relief Plus Multi-Symptom Cold

OUR PHARMACISTS RECOMMEND

FEVER REDUCER - PAIN RELIEVER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

NASAL DECONGESTANT - PHENYLEPHRINE HCl

ANTIHISTAMINE - CHLORPHENIRAMINE MALEATE

Cold & Flu Symptom Relief

Runny & Stuffy Nose

Aches & Pains

Fever

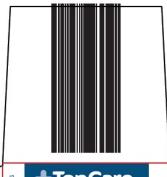
Sore Throat

Cough

Ages 6 to under 12 Years

GRAPE FLAVOR

4 FL OZ (118 mL)





TRIACTING SUSPENSION





ARE TO CHILDREN'S TRIAMINIC® MULTI-SYMPTOM FEVER & COLD ACTIVE INGREDIENTS'

TRIACTING SUSPENSION

children's **Pain Relief Plus** Multi-Symptom

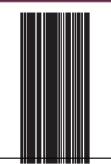
FEVER REDUCER - PAIN RELIEVER - ACETAMINO PHEN COUGHSUPPRESSANT-DEXTROMETHORPHAN HBr NASAL DECONGESTANT - PHENYLEPHRINE HCI ANTIHISTAMINE - CHLORPHENIRAMINE MALEATE

Cold & Flu Symptom Relief

- Runny & Stuffy Nose
- Aches & Pains
- Fever
- Sore Throat
- Cough



4 FL OZ (118 mL)





SUSTAINABLE FORESTRY INITIATIVE Certified Sourcing www.sfiprogram.org SFI-01052

Drug Facts

Active ingredients (In each 5 mL)

Purposes

Chlorpheniramine maleate 1 mg... Dextromethorphan HBr 5 mg...... Phenylephrine HCl 2.5 mg.....Antihistamine ...Cough suppressant ..Nasal decongestant

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Drug Facts (continued)

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Inactive ingredients appydrous citric acid. discrive in the transmission of the control of the phosphate, xanthan gum

Questions or comments? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 ©TOPCO PER917 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com





*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Children's Triaminic® Multi-Symptom Fever & Cold.

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90326 88 C8

TOPCARE COLD

acetaminophen, chlorpheniramine maleate, dextromethorphan hbr, phenylephrine hcl suspension

ORAL

Product Information

Route of Administration

HUMAN OTC DRUG NDC:36800-903 Product Type Item Code (Source)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	160 mg in 5 mL
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
CALCIUM SULFATE (UNII: WAT0 DDB 505)		
CARRAGEENAN (UNII: 5C69 YCD2YJ)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCROSE (UNII: C151H8M554)		
SODIUM PHO SPHATE, TRIBASIC (UNII: A752Q30A6X)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	PURPLE (opaque)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:36800-903-26	1 in 1 CARTON	07/24/2009	
	1	118 mL in 1 BOTTLE; 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	07/24/2009	

Revised: 1/2018 Topco Associates LLC