TOPCARE CHILDRENS COLD AND COUGH AND RUNNY NOSE- acetaminophen, chlorpheniramine maleate, and dextromethorphan hydrobromide suspension
Topco Associates, LLC

Topcare Children's Cold & Cough & Runny Nose Relief

Drug Facts

Active ingredients (in each 5 mL)	***Purposes***
Acetaminophen 160 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 1 mg	Antihistamine
Dextromethorphan HBr 5 mg	Cough suppressant

Uses

- temporarily relieves the following cold/flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - sneezing and runny nose
  - cough
- 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

- with any other drug containing acetaminophen (prescription or nonprescription). If

you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- if your child has ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if your child has
- liver disease
- a breathing problem such as chronic bronchitis
- glaucoma
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if your child is
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- **do not exceed recommended dose (see**overdose warning**)**
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

Stop use and ask a doctor if
- pain or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- 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) Quick medical attention is critical for adults as well as for children 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**

- mL = milliliter
- find the right dose on chart below. If possible, use weight to dose; otherwise, use age.
- remove the child protective cap and squeeze your child's dose into the dosing cup
- repeat dose every 4 hours, while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (mL)
under 36	under 4 years	do not use
36-47	4 to 5 years	do not use unless directed by a doctor
48-95	6 to 11 years	10 mL

Attention:use only enclosed dosing cup specifically designed for use with this product. Do not use any other dosing device.

Other information

- **each 5 mL contains:**sodium 3 mg
- store at room temperature

TAMPER-EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS TORN OR MISSING

Inactive ingredients

citric acid, carboxymethylcellulose sodium, D&C Red No. 33, edetate disodium, FD&C Blue No. 1, FD&C Red No. 40, flavors, glycerin, microcrystalline cellulose, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol solution, sucrose, xanthan gum

Questions or comments?

1-866-467-2748

PRINCIPAL DISPLAY PANEL

COMPARE TO THE ACTIVE INGREDIENTS IN CHILDREN’S TYLENOL® COLD + COUGH + RUNNY NOSE*

NDC 76162-792-04

Children's

Cold & Cough & Runny Nose Relief

ORAL SUSPENSION

ACETAMINOPHEN -PAIN RELIEVER-FEVER REDUCER

CHLORPHENIRAMINE MALEATE -ANTIHISTAMINE
DEXTROMETHORPHAN HBR -COUGH SUPPRESSANT

RELIEVES

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

GRAPE FLAVOR

NATURALLY AND ARTIFICIALLY FLAVORED

Ages 6-11 Years

4 FL OZ (120 mL)

IMPORTANT: Keep this carton for future reference on full labeling.

TAMPER-EVIDENT: DO NOT USE IF PRINTED INNER SEAT UNDER CAP IS TORN OR MISSING.

Distributed by:

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Children's Tylenol ®Cold + Cough + Runny Nose.

TOPCARE CHILDRENS COLD AND COUGH AND RUNNY NOSE

acetaminophen, chlorpheniramine maleate, and dextromethorphan hydrobromide suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76162-792
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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	purple	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-792-04	1 in 1 CARTON	08/12/2024	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/12/2024	

Labeler - Topco Associates, LLC (006935977)

Revised: 8/2024 Topco Associates, LLC