TOPCARE DAY TIME COLD AND FLU- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled 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. Day Time Cold & Flu Drug Facts

Active ingredients (in each liquid cap)

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer Cough suppressant Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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, lasts 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.
- if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 7 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.

If pregnant or breast-feeding,

ask a health professional before use.

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

- take only as directed see overdose warning
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	2 liquid caps with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Inactive ingredients

edible dye-free ink*, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO VICKS® DAYQUIL® COLD & FLU ACTIVE INGREDIENTS MULTI-SYMPTOM RELIEF Day Time Cold & Flu Relief OUR PHARMACISTS RECOMMEND PAIN RELIEVER - FEVER REDUCER - ACETAMINOPHEN COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr • NASAL DECONGESTANT -PHENYLEPHRINE HCl **DYE-FREE** Free of Artifical Dyes and Preservatives Alcohol Free Antihistamine Free Non-Drowsy Headache, Fever, Sore Throat, Minor Aches & Pains Nasal Congestion • Cough **16 LIQUID CAPS**

actual size



TOPCARE DAY TIME COLD AND FLU acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:36800-593 **Route of Administration** ORAL **Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN 325 mg DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9KYH) DEXTROMETHORPHAN 10 mg (DEXTROMETHORPHAN - UNII:7355X3ROTS) HYDRO BRO MIDE PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -PHENYLEPHRINE 5 mg UNII:1WS297W6MV) **HYDROCHLORIDE Inactive Ingredients Ingredient** Name Strength GELATIN (UNII: 2G86QN327L) GLYCERIN (UNII: PDC6A3C0OX) POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) **POVIDONE** (UNII: FZ989GH94E) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KO0R) SORBITAN (UNII: 6092ICV9RU) SORBITOL (UNII: 506T60A25R) **Product Characteristics** Color YELLOW (clear) no score Score Shape OVAL Size 21mm Flavor **Imprint** Code 7G1 Contains Packaging Item Code **Package Description** Marketing Start Date Marketing End Date # 1 NDC:36800-593-73 8 in 1 CARTON 07/25/2017

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
part341	07/25/2017		
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date	

2 in 1 BLISTER PACK; Type 0: Not a Combination Product

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Labeler - Topco Associates LLC (006935977)

Revised: 12/2019

Topco Associates LLC