### TOPCARE DAY TIME- 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.

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# Topco Associates LLC. Day Time Drug Facts

# Active ingredients (in each softgel)

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:

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

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

# 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 softgels with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

# Other information

• store at 20-25°C (68-77°F)

### Inactive ingredients

edible ink\*, FD&C red no. 40, FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

### **Questions or comments?**

### 1-888-423-0139

### **Principal Display Panel**

TopCare<sub>®</sub> health

COMPARE TO VICKS<sup>®</sup> DAYQUIL<sup>®</sup> COLD & FLU ACTIVE INGREDIENTS

MULTI-SYMPTOM RELIEF

Day Time

Cold & Flu Relief

PAIN RELIEVER – FEVER REDUCER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

NASAL DECONGESTANT - PHENYLEPHRINE HCI

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal Congestion

Cough

Alcohol Free

Antihistamine Free

Non-Drowsy

24 SOFTGELS

actual size



# TOPCARE DAY TIME acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-700 Route of Administration ORAL V V V Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg
(********************************	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZ B9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6092ICV9RU)			

Product Characteristics						
Color	ORANGE	Score	no score			
Shape	OVAL	Size	20mm			
Flavor		Imprint Code	L994			
Contains						

# Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:36800-700- 53	6 in 1 CARTON	10/06/2006	10/06/2006		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:36800-700- 60	10 in 1 CARTON	09/28/2006	09/28/2006		
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product				
3	NDC:36800-700- 73	8 in 1 CARTON	08/07/2012			
3		2 in 1 BLISTER PACK; Type 0: Not a Combination Product				
4	NDC:36800-700- 62	12 in 1 CARTON	08/09/2012			
4		2 in 1 BLISTER PACK; Type 0: Not a Combination Product				
M	Marketing Information					

Marketing Category

09/28/2006

# Labeler - Topco Associates LLC (006935977)

Revised: 3/2023

Topco Associates LLC