

# **DAYTIME COLD AND FLU RELIEF- daytime cold and flu relief capsule, liquid filled**

**TopCo Associates, LLC**

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**417 - Daytime Cold and Flu Relief**

## **Active ingredient(s)**

**Acetaminophen 325mg**

Dextromethorphan HBr 10mg

Phenylephrine HCl 5mg

## **Purpose**

**Pain reliever/fever reducer**

Cough suppressant

Nasal decongestant

## **Use(s)**

- temporarily relieves common cold/flu symptoms:
- • nasal congestion
- • cough due to minor throat & bronchial irritation
- • sore throat
- • headache
- • minor aches & pains
- • fever

## **Warnings**

**Liver warning:** This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- 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, persists for more than 2 days, occurs with or is 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

### **Ask a doctor before use if**

- liver disease • heart disease • thyroid disease • diabetes • high blood pressure
- 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**

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
  - symptoms get worse or last more than 5 days (children) or 7 days (adults)
  - 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 breastfeeding,**

ask a health professional before use.

### **Keep out of reach of children**

Taking more than directed can cause serious health problems. 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 adults as well as for children, even if you do not notice any signs or symptoms.

### **Directions**

- Take only as directed
- Do not exceed 4 doses in 24 hours

**adults and children 12 years & over:** 2 softgels with water every 4 hours

**children 4 to under 12 years:** ask a doctor

**children under 4 years:** do not use

**Other information**

- store at room temperature 20-25 °C (68-77° F)
- do not use if blister unit is torn or open

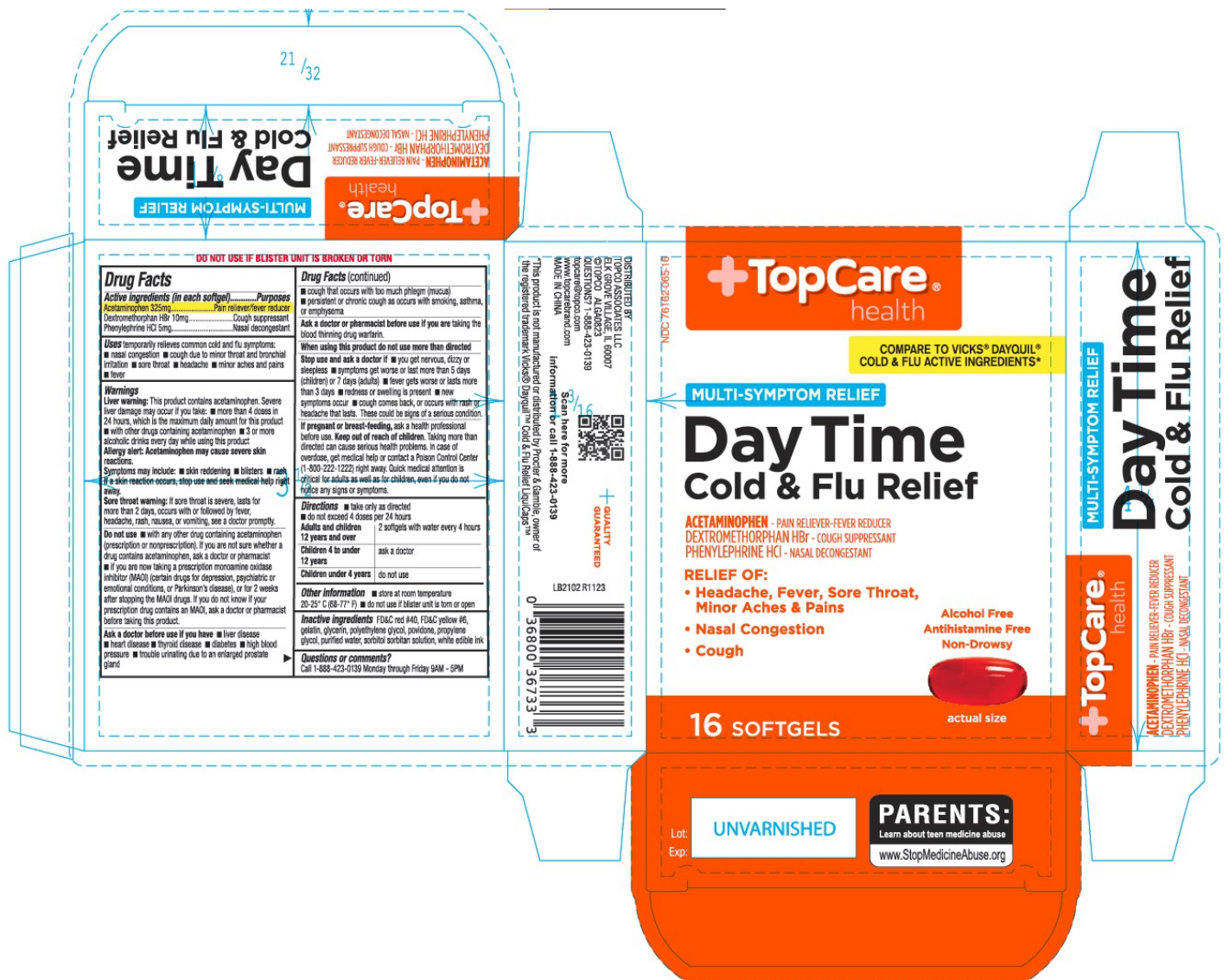
**Inactive ingredients**

FD&C red #40, FD&C yellow #6,  
gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, white edible ink

**Questions/Comments**

Call 1-888-952-0050 Monday through Friday 9AM - 5PM

**Principal Display Panel**



Daytime Cold and Flu

## DAYTIME COLD AND FLU RELIEF

daytime cold and flu relief capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76162-065
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	

## Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	PC9
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-065-16	1 in 1 CARTON	11/03/2023	
1		16 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/03/2023	

**Labeler** - TopCo Associates, LLC (006935977)

Revised: 10/2023

TopCo Associates, LLC