

**TOPCARE NITE TIME DAY TIME COLD AND FLU- acetaminophen,  
dextromethorphan hbr, doxylamine succinate, phenylephrine hcl  
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. Nite Time Day Time Cold & Flu Drug Facts**

**Active ingredients (in each softgel) - Nitetime Cold & Flu**

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Active ingredients (in each softgel) - Daytime Cold & Flu**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Purpose - Nitetime Cold & Flu**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

**Purpose - Daytime Cold & Flu**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

**Uses - Nitetime Cold & Flu**

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- runny nose and sneezing

- fever

## **Uses - Daytime Cold & Flu**

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- sore throat
- headache
- nasal congestion
- 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 - Nighttime Cold & Flu**

- liver disease
- glaucoma

- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

### **Ask a doctor before use if you have - Daytime Cold & Flu**

- liver disease
- diabetes
- heart disease
- high blood pressure
- thyroid disease
- 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 - Nighttime Cold & Flu**

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

### **Ask a doctor or pharmacist before use if you are - Daytime Cold & Flu**

taking the blood thinning drug warfarin

### **When using this product**

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

### **When using this product - Daytime Cold & Flu**

**do not use more than directed**

### **Stop use and ask a doctor if - Nighttime Cold & Flu**

- pain 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.

### **Stop use and ask a doctor if - Daytime Cold & Flu**

- 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 - Nitetime Cold & Flu**

- 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 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

**Directions - Daytime Cold & Flu**

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**Other information**

- store at 20-25°C (68-77°F)

**Inactive ingredients - Nitetime Cold & Flu**

D&C yellow no. 10, edible ink\*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

**Inactive ingredients - Daytime Cold & Flu**

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 - Daytime**

SPECIAL VALUE! COMBINATION PACK

Top Care® health

COMPARE TO VICKS® DAYQUIL® COLD & FLU ACTIVE INGREDIENTS

MULTI-SYMPTOM RELIEF

Day Time Cold & Flu Relief

PAIN RELIEVER – FEVER REDUCER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

NASAL DECONGESTANT - PHENYLEPHRINE HCl

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

Alcohol Free

Antihistamine Free

Non-Drowsy

actual size

32 SOFTGELS

Top Care® health

COMPARE TO VICKS® NYQUIL® COLD & FLU ACTIVE INGREDIENTS

MULTI-SYMPTOM RELIEF

Nite Time Cold & Flu Relief

PAIN RELIEVER – FEVER REDUCER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

ANTIHISTAMINE - DOXYLAMINE SUCCINATE

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sneezing, Runny Nose
- Cough

Alcohol Free

actual size

16 SOFTGELS



68072 88 CS

**CODE AREA**

OPEN OTHER END

Nighttime Cold & Flu	Daytime Cold & Flu																
<p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Active Ingredients (in each softgel)</th> <th style="width: 40%;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen 325 mg</td> <td>Pain relief/fever reducer</td> </tr> <tr> <td>Dextromethorphan HBr 15 mg</td> <td>Cough suppressant</td> </tr> <tr> <td>Doxylamine succinate 6.25 mg</td> <td>Antihistamine</td> </tr> </tbody> </table> <p><b>Uses:</b> Temporarily relieves common cold/flu symptoms:</p> <ul style="list-style-type: none"> <li>■ cough due to minor throat and bronchial irritation</li> <li>■ minor aches and pains ■ sore throat ■ headache</li> <li>■ runny nose and sneezing ■ fever</li> </ul> <p><b>Warnings</b></p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>■ more than 4,000 mg of acetaminophen in 24 hours</li> <li>■ with other drugs containing acetaminophen</li> <li>■ 3 or more alcoholic drinks every day while using this product</li> </ul> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p>	Active Ingredients (in each softgel)	Purpose	Acetaminophen 325 mg	Pain relief/fever reducer	Dextromethorphan HBr 15 mg	Cough suppressant	Doxylamine succinate 6.25 mg	Antihistamine	<p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Active Ingredients (in each softgel)</th> <th style="width: 40%;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen 325 mg</td> <td>Pain relief/fever reducer</td> </tr> <tr> <td>Dextromethorphan HBr 10 mg</td> <td>Cough suppressant</td> </tr> <tr> <td>Phenylephrine HCl 5 mg</td> <td>Nasal decongestant</td> </tr> </tbody> </table> <p><b>Uses:</b> Temporarily relieves common cold/flu symptoms:</p> <ul style="list-style-type: none"> <li>■ cough due to minor throat and bronchial irritation</li> <li>■ minor aches and pains ■ sore throat ■ headache</li> <li>■ nasal congestion ■ fever</li> </ul> <p><b>Warnings</b></p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> <li>■ more than 4,000 mg of acetaminophen in 24 hours</li> <li>■ with other drugs containing acetaminophen</li> <li>■ 3 or more alcoholic drinks every day while using this product</li> </ul> <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash</p> <p>If a skin reaction occurs, stop use and seek medical help right away.</p>	Active Ingredients (in each softgel)	Purpose	Acetaminophen 325 mg	Pain relief/fever reducer	Dextromethorphan HBr 10 mg	Cough suppressant	Phenylephrine HCl 5 mg	Nasal decongestant
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DISTRIBUTED BY  
TOPCO ASSOCIATES LLC  
110 GROVEVILLE, IL 60007  
www.topcare.com 1-888-423-0139  
topcare@topcare.com  
MADE IN CANADA

GLUTEN FREE

PARENTS: [www.doublecheckstore.com](http://www.doublecheckstore.com)

Scan here for more information or call 1-888-423-0139

QUALITY GUARANTEED

CONVENIENT RECYCLING TAB

## TOPCARE NITE TIME DAY TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-580
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-580-72	1 in 1 CARTON; Type 0: Not a Combination Product	04/29/2014	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
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<b>Part 1</b>	8 BLISTER PACK	16
<b>Part 2</b>	16 BLISTER PACK	32

## Part 1 of 2

### TOPCARE NITE TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

#### Product Information

**Item Code (Source)** NDC:36800-143

**Route of Administration** 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	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

#### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

#### Product Characteristics

<b>Color</b>	GREEN (clear)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	056
<b>Contains</b>			

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:36800-143-73	8 in 1 CARTON		
1		2 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 final	part341	02/02/2014	

## Part 2 of 2

### TOPCARE DAY TIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

## Product Information

**Route of Administration** 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, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

## Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm

<b>Flavor</b>		<b>Imprint Code</b>	L994
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/28/2006	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/29/2014	

**Labeler** - Topco Associates LLC (006935977)