

**TOPCARE NITE TIME DAY TIME COLD AND FLU- acetaminophen,  
dextromethorphan hbr, doxylamine succinate, phenylephrine hcl  
Topco Associates LLC**

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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**

- 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 - 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



**VISIBLE PRINT AREA**

**SPECIAL VALUE! COMBINATION PACK**

NDC 368800-980-72



COMPARE TO VICKS® DAYQUIL®  
COLD & FLU ACTIVE INGREDIENTS\*\*

COMPARE TO VICKS® NYQUIL®  
COLD & FLU ACTIVE INGREDIENTS\*\*

**MULTI-SYMPTOM RELIEF**

**MULTI-SYMPTOM RELIEF**

# Day Time Cold & Flu Relief

# Nite Time Cold & Flu Relief

PAIN RELIEVER-FEVER REDUCER -  
**ACETAMINOPHEN**  
COUGH SUPPRESSANT -  
**DEXTROMETHORPHAN HBr**  
NASAL DECONGESTANT -  
**PHENYLEPHRINE HCl**

PAIN RELIEVER-FEVER REDUCER -  
**ACETAMINOPHEN**  
COUGH SUPPRESSANT -  
**DEXTROMETHORPHAN HBr**  
ANTIHISTAMINE -  
**DOXYLAMINE SUCCINATE**

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

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

Alcohol Free  
Antihistamine Free  
Non-Drowsy

Alcohol Free



**32**  
SOFTGELS

actual size

**16**  
SOFTGELS

actual size



**CODE AREA**

58072 88 CS

0 58072 88 009

OPEN OTHER END

Nighttime Cold & Flu	Daytime Cold & Flu
<p><b>Drug Facts</b></p> <p><b>Active Ingredients (in each softgel)</b></p> <p>Acetaminophen 325 mg Pain reliever/fever reducer</p> <p>Dextromethorphan HBr 15 mg Cough suppressant</p> <p>Doxylamine succinate 6.25 mg Antihistamine</p> <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><b>Liver warning:</b> 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><b>Allergy alert:</b> 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>	<p><b>Drug Facts</b></p> <p><b>Active Ingredients (in each softgel)</b></p> <p>Acetaminophen 325 mg Pain reliever/fever reducer</p> <p>Dextromethorphan HBr 10 mg Cough suppressant</p> <p>Phenylephrine HCl 5 mg Nasal decongestant</p> <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><b>Liver warning:</b> 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><b>Allergy alert:</b> 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>
<p><b>Drug Facts (continued)</b></p> <p><b>Sore throat warning:</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or anesthetic 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.</li> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients</li> </ul> <p><b>Ask a doctor before use if you have</b> ■ liver disease ■ glaucoma</p> <ul style="list-style-type: none"> <li>■ cough that occurs with too much phlegm (mucus)</li> <li>■ a breathing problem such as asthma or chronic bronchitis</li> <li>■ persistent or chronic cough as occurs with smoking, asthma, or emphysema</li> <li>■ trouble urinating due to an enlarged prostate gland</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b> ■ taking sedative or tranquilizers ■ taking the blood thinning drug warfarin</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ excitability may occur, especially in children</li> <li>■ marked drowsiness may occur ■ avoid alcoholic drinks</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> <li>■ alcohol, sedatives, and tranquilizers may increase drowsiness</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ pain or cough gets worse or lasts more than 7 days</li> <li>■ fever gets worse or lasts more than 3 days</li> <li>■ redness or swelling is present ■ new symptoms occur</li> <li>■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Sore throat warning:</b> 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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or anesthetic 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.</li> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients</li> </ul> <p><b>Ask a doctor before use if you have</b> ■ liver disease ■ diabetes</p> <ul style="list-style-type: none"> <li>■ heart disease ■ high blood pressure ■ thyroid disease</li> <li>■ trouble urinating due to an enlarged prostate gland</li> <li>■ cough that occurs with too much phlegm (mucus)</li> <li>■ persistent or chronic cough as occurs with smoking, asthma, or emphysema</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b> ■ taking the blood thinning drug warfarin</p> <p><b>When using this product do not use more than directed</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ you get nervous, dizzy or sleepless</li> <li>■ pain, nasal congestion or cough gets worse or lasts more than 7 days</li> <li>■ fever gets worse or lasts more than 3 days</li> <li>■ redness or swelling is present</li> <li>■ new symptoms occur</li> <li>■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.</li> </ul>
<p><b>Drug Facts (continued)</b></p> <p>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.</p> <p><b>Directions</b></p> <p>take only as directed - see overdose warning</p> <p>do not exceed 4 doses per 24 hrs</p> <p>adults &amp; children 12 yrs &amp; over 2 softgels with water every 6 hrs</p> <p>children 4 to under 12 yrs ask a doctor</p> <p>children under 4 yrs do not use</p> <p><b>Other information</b> ■ store at 20-25°C (68-77°F)</p> <p><b>Inactive ingredients:</b> For D&amp;C yellow no. 10, soluble ink, FD&amp;C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sodium sulfite solution *may contain this ingredient</p> <p><b>Questions or comments?</b> 1-888-423-0139</p>	<p><b>Drug Facts (continued)</b></p> <p>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.</p> <p><b>Directions</b></p> <p>take only as directed - see overdose warning</p> <p>do not exceed 4 doses per 24 hrs</p> <p>adults &amp; children 12 yrs &amp; over 2 softgels with water every 4 hrs</p> <p>children 4 to under 12 yrs ask a doctor</p> <p>children under 4 yrs do not use</p> <p><b>Other information</b> ■ store at 20-25°C (68-77°F)</p> <p><b>Inactive ingredients:</b> For soluble ink, FD&amp;C red no. 40, FD&amp;C yellow no. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sodium sulfite solution *may contain this ingredient</p> <p><b>Questions or comments?</b> 1-888-423-0139</p>

**GLUTEN FREE**

**QUALITY GUARANTEED**

**CONVENIENT RECYCLING TAB**

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

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11550 W. 112th St., Suite 100  
Overland Park, KS 66213-1120  
www.topcarebrand.com  
MADE IN CANADA

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Learn about medication abuse.  
www.SafeMedicationAbuse.org

## 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
Part 1	8 BLISTER PACK	16

**Part 1 of 2****TOPCARE NITE TIME COLD AND FLU**

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

**Product Information**

<b>Item Code (Source)</b>	NDC:36800-143
<b>Route of Administration</b>	ORAL

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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**

<b>Ingredient Name</b>	<b>Strength</b>
<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**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:36800-143-	0 in 1 CARTON		

73	6 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 Drug	M012	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

**Contains****Packaging**

#	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		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/28/2006	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/29/2014	

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

Revised: 11/2024

Topco Associates LLC