

**NITETIME COLD FLU RELIEF- acetaminophen, dextromethorphan hydrobromide,  
doxylamine succinate capsule, liquid filled  
Care One (American Sales Company)**

*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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**Drug Facts**

**Active ingredients (in each softgel)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Purpose**

**Pain reliever/fever reducer**

Cough suppressant

Antihistamine

**Uses**

- temporarily relieves common cold and flu symptoms:
  - sore throat
  - headache
  - minor aches and pains
  - fever
  - runny nose and sneezing
  - cough due to minor throat and bronchial irritation

**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

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

**Do not use**

- to make a child sleep
- 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.

**Ask a doctor before use if you have**

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

**Ask a doctor or pharmacist before use if you are**

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

**When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

- 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.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center 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**

- **do not take more than directed (see Overdose warning )**
- do not take more than 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- swallow whole; do not crush, chew, or dissolve
- children under 12 years: do not use
- **when using other Daytime or Nitetime products, carefully read each label to insure correct dosing**

**Other information**

- store at room temperature 15°-30°C (59°-86°F)
- avoid excessive heat

**Inactive ingredients**

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol

**Questions or comments?**

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

**Principal Display Panel**

Compare to the Active Ingredients in Vicks® NyQuil® LiquiCaps®\*  
Multi-Symptom

**NITETIME LIQUID CAPS COLD/FLU RELIEF**

PAIN RELIEVER- FEVER REDUCER [ACETAMINOPHEN]

COUGH SUPPRESSANT [DEXTROMETHORPHAN HBr]

ANTIHISTAMINE [DOXYLAMINE SUCCINATE]

SOFTGELS

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LANDOVER, MD 20785

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IS BLISTER UNIT IF TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

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**Product Label**

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■ swallow whole; do not crush, chew, or dissolve  
■ children under 12 years: do not use  
■ when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

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**Keep out of reach of children.**  
**If pregnant or breast-feeding,** ask a health professional before use.

**Drug Facts (continued)**  
■ cough comes back or occurs with rash or headache that lasts  
These could be signs of a serious condition.  
■ **Do not use** if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist before taking this product.

**Drug Facts (continued)**  
■ **Do not use** if you are not sure whether a drug contains acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist before taking this product.  
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**CAREONE®**

**MULTI-SYMP TOM**

**NITETIME**

**LIQUID CAPS**

**COLD/FLU RELIEF**

Pain Reliever-Fever Reducer [Acetaminophen]  
Cough Suppressant [Dextromethorphan HBr]  
Antihistamine [Doxylamine Succinate]

**24**  
**SOFTGELS**

Compare to the Active Ingredients in Vicks® NyQuil® LiquiCaps®\*

CAREONE® MULTI-SYMP TOM NITETIME

Acetaminophen  
Dextromethorphan HBr  
Doxylamine Succinate

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Care One Nitetime Cold Flu Relief Softgels

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Lot No.:  
Exp. Date:

# NITETIME COLD FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-445
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	GREEN	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	P30;94A;SCU1
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-445-24	24 in 1 CARTON	06/03/2013	
1		1 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	06/03/2013	

**Labeler** - Care One (American Sales Company) (809183973)

Revised: 6/2019

Care One (American Sales Company)