

**DAYTIME NIGHTTIME COLD FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl  
Care One (Retail Business Services, LLC.)**

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**DRUG FACTS**

**Active ingredients for Daytime (in each softgel)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Active ingredients for Nighttime (in each softgel)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Purpose for Daytime**

**Pain reliever/fever reducer**

Cough suppressant

Nasal decongestant

**Purpose for Nighttime**

**Pain reliever/fever reducer**

Cough suppressant

Antihistamine

**Uses**

**DAYTIME**

- temporarily relieves common cold and flu symptoms
  - cough due to minor throat and bronchial irritation
  - fever
  - sore throat
  - nasal congestion and sinus pressure
  - headache
  - minor aches and pains

**NIGHTTIME**

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

## Warnings

### DAYTIME

**Liver warning:** These products contain 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 these products

**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, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

### NIGHTTIME

**Liver warning:** This product contain acetaminophen. Severe liver damage may occur if you take:

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- 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, is accompanied or following by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

## Do not use

### DAYTIME

- 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.

### **NIGHTTIME**

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- 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**

#### **DAYTIME**

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

#### **NIGHTTIME**

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

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

#### **DAYTIME**

taking the blood thinning drug warfarin

#### **NIGHTTIME**

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

### **When using this product,**

#### **DAYTIME**

**do not exceed recommended dosage.**

## **NIGHTTIME**

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

## **Stop use and ask a doctor if**

### **DAYTIME**

- nervousness, dizziness or sleeplessness occur
- pain, cough, and nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

### **NIGHTTIME**

- 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 headache that lasts.

These could be a 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 (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**

### **DAYTIME**

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over; take 2 softgels with water every 4 hours.
- children under 12 years: do not use

### **NIGHTTIME**

- do not take more than directed (see Overdose warning)

- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

### **Other information**

- store between 15°-30°C (59°-86°F)
- avoid excessive heat

### **Inactive ingredients**

#### **DAYTIME**

FD&C red #40, FD&C yellow #6, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

#### **NIGHTTIME**

D&C yellow #10, FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

### **Questions or comments?**

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

### **Principal Display Panel**

Compare to the active ingredients in Vicks® Dayquil™ and Nyquil™ Cold & Flu LiquiCaps™ †

#### **DAYTIME**

#### **MULTI-SYMPTOM**

#### **COLD / FLU RELIEF**

Pain reliever / Fever Reducer - Acetaminophen

Cough Suppressant - Dextromethorphan HBr

Nasal Decongestant - Phenylephrine HCl

Relieves Cold & Flu Symptoms:

Aches & Fever, Sore Throat, Coughing, Congestion & Sinus Pressure

SOFTGELS

#### **NIGHTTIME**

#### **MULTI-SYMPTOM**

#### **COLD / FLU RELIEF**

Pain Reliever/ Fever Reducer - Acetaminophen

Cough Suppressant - Dextromethorphan HBr

Antihistamine - Doxylamine Succinate

Relieves Cold & Flu Symptoms

So You Can Rest

SOFTGELS

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

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

**When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.**

DISTRIBUTED BY

ADUSA DISTRIBUTION, LLC

SALISBURY, NC 28147

**Product Label**



Aches & Fever, Sore Throat, So You Can Rest  
Coughing, Congestion & Sinus Pressure

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.

**48 TOTAL SOFTGELS**    **32 DAYTIME SOFTGELS, 16 NIGHTTIME SOFTGELS**



PLD-F588C FC009679

Quality guaranteed or your money back.  
contact us at 1-833-992-3872  
For product questions or concerns,  
SALISBURY, NC 28147  
ADUSA DISTRIBUTION, LLC  
DISTRIBUTED BY:

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

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

The product is not manufactured or distributed by The Procter & Gamble Company. "Vicks", DayQuil™, NyQuil™, and LiquiCap™ are registered trademarks of The Procter & Gamble Company.  
www.StephensonPharma.com  
PARENTS: Learn how to best protect your child

**Daytime Cold & Flu Softgel**    **Nighttime Cold & Flu Softgel**

**Drug Facts (continued)**

**Other Information**  
■ store between 15-30°C (59-86°F)  
■ avoid excessive heat

**Inactive Ingredients** D&C yellow #10, FD&C blue #1, gelatin, glycerin, lactose, light mineral oil, mannitol, polyethylene glycol, polyethylene glycol, purified water, sorbitan, sorbitol, white ink

**Questions or comments?**  
Call 1-877-753-3835 Monday-Friday 9AM-5PM EST

**CAREONE Daytime Nighttime Multi-Symptom Cold /Flu relief**

**DAYTIME NIGHTTIME COLD FLU RELIEF**

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-901
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-901-48	1 in 1 KIT; Type 0: Not a Combination Product	09/30/2019	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	16 BLISTER PACK	16
Part 2	32 BLISTER PACK	32

# NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule

## 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	15 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (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</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>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	PC10
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
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 Drug	M012	09/30/2019	

## Part 2 of 2

### DAYTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

## 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</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>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	

## Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	PC9
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		32 in 1 CARTON		
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 Drug	M012	09/30/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/30/2019	

**Labeler** - Care One (Retail Business Services, LLC.) (967989935)

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Care One (Retail Business Services, LLC.)