

DAYTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, phenylephrine hcl 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.

DRUG FACTS

Active Ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan Hydrobromide 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/Fever reducer

Cough suppressant

Nasal decongestant

Uses

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 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday while using this product.

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea or vomiting, see a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or non prescription). 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
- 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 you are

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 breast-feeding

ask a health professional before use.

Keep out of reach of children.

Overdose warning: Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a poison control center right away. Quick medical attention is critical for adults and for children even if you do not notice any signs or symptoms.

Directions

- take only as directed- see overdose warning
- do not exceed 4 doses per 24 hours

adults and children 12 years and over	swallow 2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

- **when using other daytime or nighttime products, carefully read each label to insure correct dosing**

Other information

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

Inactive Ingredients

butylated hydroxyanisole, butylated hydroxytoluene, edible white printing ink, FD&C Red #40*, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, and sorbitol

*May contain this ingredient

Questions or comments?

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

Product Labeling

Compare to active ingredients in Vicks® Dayquil® **

**This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® DayQuil®

Non- drowsy

daytime liquid caps multi symptom cold/ flu relief

acetaminophen, dextromethorphan hydrobromide, phenylephrine HCl
pain reliever, fever reducer, cough suppressant, nasal congestant

Relieves major cold and flu symptoms

Aches & fever, sore throat, coughing, congestion

Distributed by

American sales company

4201 walden avenue

Lancaster NY 14086

1-877-846-9949

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

NO INK
NO VARNISH

NO INK
NO VARNISH

Drug Facts (continued)

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 breast-feeding, ask a health professional before use. Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults and for children even if you do not notice any signs or symptoms.

Directions ■ Take only as directed—see Overdose warning ■ do not exceed 4 doses per 24 hours ■ adults and children swallow 2 softgels with water every 4 hours ■ children 4 to under 12 years ask a doctor ■ children under 4 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) and avoid excessive heat

Inactive ingredients butylated hydroxytoluene, butylated hydroxyanisole, #40, FD&C Yellow #6, gelatin, glycerin, polyethylene glycol, polyvinyl alcohol, propylene glycol, purified water, sorbitan, and sorbitol. They contain this ingredient.

Drug Facts

Active ingredients (in each softgel) Purpose

Acetaminophen 325 mg Pain reliever/fever reducer
 Dextromethorphan Hydrobromide 10 mg Cough suppressant
 Phenylephrine HCl 5 mg Nasal decongestant

Uses Temporarily relieves common cold/flu symptoms: ■ nasal congestion ■ cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever

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Ask a doctor before use if you have ■ liver disease ■ heart disease ■ thyroid disease ■ diabetes ■ high blood pressure ■ trouble urinating due to 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 taking the blood thinning drug warfarin.

CAREONE® Non-Drowsy **DAYTIME**
 Acetaminophen,
 Dextromethorphan HBr,
 Phenylephrine HCl

Compare to the Active Ingredients in Vicks® DayQuil®**

CAREONE®
 Non-Drowsy
DAYTIME
 LIQUID CAPS

MULTI SYMPTOM COLD/FLU RELIEF

Acetaminophen
 Dextromethorphan HBr, Phenylephrine HCl
 Pain Reliever, Fever Reducer, Cough Suppressant,
 Nasal Decongestant
 Relieves Major Cold & Flu Symptoms:
 Aches & Fever, Sore Throat, Coughing,
 Congestion

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SOFTGELS

Drug Facts (continued)
Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Lot No.:
Exp. Date:

DISTRIBUTED BY
 AMERICAN SALES COMPANY
 4201 WALDEN AVENUE
 LANCASTER, NY 14086
 1-877-846-9949
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 Quality guaranteed or your money back.
 PLD-A
 FC000816



Daytime liquid caps cold and flu relief

DAYTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-473
Route of Administration	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	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	ORANGE	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	P19;95A;36A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-473-24	2 in 1 CARTON	11/15/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41520-473-16	2 in 1 CARTON	11/15/2012	
2		8 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	11/15/2012	

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

Revised: 10/2012

Care One (American Sales Company)