

**NIGHTTIME COLD AND FLU- acetaminophen dextromethorphan hbr
doxylamine succinate capsule, liquid filled
Care One (Retail Business Services, LLC.)**

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 everyday 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 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.

Ask a doctor before use if you have

- liver disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts 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 (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

- **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 Nighttime products, carefully read each label to insure correct dosing**

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, 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® NyQuil® Cold & Flu LiquiCaps®

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

Alcohol-Free

SOFTGELS**

(**LIQUID-FILLED CAPSULES)

†This product is not manufactured or distributed by The Procter & Gamble Company.

Vicks®, NyQuil®, and LiquiCaps® are registered trademark of the Procter & Gamble Company

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY:

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

Package Label

CAREone
NDC 72476-899-24

**Compare to the active ingredients in Vicks® NyQuil® Cold & Flu LiquiCaps®*

NIGHTTIME MULTI-SYMPATOM COLD & FLU RELIEF

Pain Reliever/Fever Reducer - **Acetaminophen**
Cough Suppressant - **Dextromethorphan HBr**
Antihistamine - **Doxylamine Succinate**

Relieves Cold & Flu Symptoms so You Can Rest

Alcohol-Free

24 SOFTGELS**
(*LIQUID-FILLED CAPSULES)

Drug Facts (continued)

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

Drug Facts (continued)

Warnings ■ 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
■ rash or other allergic reactions 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 (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 ■ do not take more than directed (see Overdose warning)
■ do not take more than 4 doses in 24 hours
■ take 1 softgel 15 minutes before bedtime
■ 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 Nighttime products, carefully read each label to ensure correct dosing

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, lecithin, light mineral oil, mannitol, polyethylene glycol, polydione, propylene glycol, purified water, sorbitan, sorbitol, white ink

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

Drug Facts (continued)

Warnings ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) such as phenelzine, tranylcypromine, or isocarboxazid, or if you have taken a MAOI in the last 14 days, 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
■ trouble urinating due to an enlarged prostate gland
■ a breathing problem or chronic cough that lasts 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
■ avoid alcohol, grapefruit juice, or other grapefruit products
■ avoid alcoholic drinks ■ marked drowsiness may occur

Drug Facts (continued)

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Lot No:
Exp. Date:

CAREONE Nighttime Cold & Flu Relief

NIGHTTIME COLD AND FLU

acetaminophen dextromethorphan hbr doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-899(NDC:51013-147)
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	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (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)	
MANNITOL (UNII: 3OWL53L36A)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Product Characteristics

Color	green (clear)	Score	no score
Shape	CAPSULE (oblong)	Size	20mm
Flavor		Imprint Code	PC10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-899-24	24 in 1 CARTON	07/01/2023	
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	07/01/2023	

Revised: 8/2024

Care One (Retail Business Services, LLC.)