

NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr and doxylamine succinate 325 mg, 15 mg and 6.25 mg capsule, liquid filled
We Care Distributor Inc.

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.

NIGHTTIME COLD AND FLU - Acetaminophen, Dextromethorphan HBr and Doxylamine Succinate

Drug Facts

Active Ingredient (in each softgel)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses

Temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- fever
- runny nose and sneezing
- sore throat
- headache

Warnings

Liver warning:

This product contains acetaminophen. The maximum daily dose of this product is 8 softgels (2,600 mg acetaminophen) in 24 hours. 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, lasts for more than 2 days, occurs with or is 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 monamine 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.

- to make a child sleepy
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- gloucoma
- 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
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

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

When using this product

- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- may cause marked drowsiness

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
- new symptoms occur
- redness or swelling is present
- 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.

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

- **take only as directed - see Liver warning**
- do not exceed 8 softgels per 24 hours
- **adults and children 12 years and over:** 2 softgels with water every 6 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 20°-25°C (68°-77°F)
- read all product information before using. Keep this box for important information

Inactive ingredients

D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, methylparaben, polyethylene glycol, povidone, propylene glycol, propylparaben, purified water, sorbitol special, sorbitol solution, titanium dioxide

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL

See New Warnings Information & Directions

Compare to the Active Ingredients in

NyQuil® LiquiCaps®

Acetaminophen, Dextromethorphan HBr and Doxylamine Succinate 325 mg, 15 mg and 6.25 mg

TO OPEN

PUSH IN TAB AND PULL OUT

25 Pouches of 2 Softgels Each

NDC: 70005-005-25

SEE NEW WARNINGS AND DIRECTIONS



NIGHTTIME COLD & FLU

COMPARE TO

NyQuil®

LIQUICAPS® ACTIVE INGREDIENTS*

Acetaminophen, 325 mg
Dextromethorphan HBr, 15 mg
Doxylamine Succinate, 6.25 mg

Cold & Flu Multi-Symptom Relief
Pain Reliever, Fever Reducer,
Cough Suppressant, Antihistamine
• **Alcohol Free**

*This product is not manufactured or distributed by Procter & Gamble, the distributor of NyQuil® LiquiCaps®

25 Pouches of 2 SoftGels

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 ■ if you have ever had an allergic reaction to this product or any of its ingredients
Ask a doctor before use if you have ■ liver disease ■ glaucoma ■ 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 ■ cough that occurs with too much phlegm (mucus)
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Stop use and ask a doctor if ■ pain or cough gets worse or lasts more than 7 days
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Drug Facts (continued)

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NIGHTTIME COLD & FLU

COMPARE TO

NyQuil®

LIQUICAPS® ACTIVE INGREDIENTS*

Acetaminophen, 325 mg
Dextromethorphan HBr, 15 mg
Doxylamine Succinate, 6.25 mg

Cold & Flu Multi-Symptom Relief
Pain Reliever, Fever Reducer,
Cough Suppressant, Antihistamine
• **Alcohol Free**

*This product is not manufactured or distributed by Procter & Gamble, the distributor of NyQuil® LiquiCaps®



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DO NOT USE IF POUCH IS BROKEN OR TORN



Manufactured For / Distributed By:
We Care Distributor Inc.
Hermitage, TN 37076
www.wecaredistributor.com

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr and doxylamine succinate 325 mg, 15 mg and 6.25 mg capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-005
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: 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: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	SN;3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-005-25	25 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-005-50	50 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-005-02	2 in 1 POUCH		
3		2 in 1 POUCH; 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	02/17/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
Softech Pharma Pvt. Ltd		677111277	manufacture(70005-005)

Revised: 3/2016

We Care Distributor Inc.