## ${\bf NIGHT\ TIME\ COLD\ AND\ FLU-\ acetamin ophen,\ dextromethor phan\ hydrobromide,\ doxylamine\ succinate\ capsule,\ liquid\ filled}$

Ameris ourceBergen (Good Neighbor Pharmacy)

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 & 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 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**

- not 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 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 Vicks® NyQuil® LiquiCaps® active ingredients

#### **Night Time Liquid Caps**

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

#### Cold & Flu

Pain Reliever-Fever Reducer

Cough Suppressant-Antihistamine

Relieves Cold and Flu-like Symptoms So You Can Rest

Softgels

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

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 AmerisourceBergen

1300 Morris Drive, Chesterbrook, PA 19087

www.goodneighborpharmacy.com

**Product Label** 

#### Call 1-877-753-3935 Monday-Friday 9AM-5PM EST Questions or comments?

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■ do not take more than directed (see Overbose warning) Directions

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\*\*Compare to Vicks\* NyQuil\* LiquiCaps\* active ingredients



NDC 46122-183-73

# Night Time Liquid Caps

acetaminophen, dextromethorphan HBr, doxylamine succinate

## Cold & Flu

Pain Reliever-Fever Reducer Cough Suppressant-Antihistamine Relieves Cold and Flu-like Symptoms So You Can Rest

Alcohol Free

16 softgels

IME Liquid Caps

Distributed By AmerisourceBergen 1300 Morris Drive, Chesterbrook, PA 19087 Visit us at www.goodneighborpharmacy.com



PLD-C FC001307

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CEEP OUTER

Date: Lot No.:

## Good Neighbor Pharmacy Night Time Cold & Flu Softgel

## NIGHT TIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-183	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg		
<b>DO XYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DO XYLAMINE - 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 GLYCOLS (UNII: 3WJQ0SDW1A)			
PO VIDO NES (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6 O 9 2 ICV 9 RU)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics				
Color	GREEN	Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	P30;94A;35A	
Contains				

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:46122-183-73	2 in 1 CARTON		
1		8 in 1 BLISTER PACK		

Marketing Inform	nation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

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OTC MONOGRAPH FINAL	part341		0 2/25/20 13	

## Labeler - AmerisourceBergen (Good Neighbor Pharmacy) (007914906)

**Registrant** - P and L Development of New York Corporation (800014821)

Revised: 5/2013 AmerisourceBergen (Good Neighbor Pharmacy)