

**NIGHTTIME COLD AND FLU RELIEF - acetaminophen, dextromethorphan hbr and doxylamine succinate capsule**  
**Chain Drug Consortium, LLC**

*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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**NIGHTTIME COLD AND FLU**

**Multi-Symptom**

***Drug Facts***

***Active ingredients (in each capsule)***

Acetaminophen USP 325 mg  
Dextromethorphan HBr USP 15 mg  
Doxylamine succinate USP 6.25 mg

***Purpose***

Pain reliever/fever reducer  
Cough suppressant  
Antihistamine

***Uses***

temporarily relieves common cold/flu symptoms:

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

***Warnings***

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

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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 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.

- to make a child sleep

**Ask a doctor before use if you have**

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

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

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

**When using this product**

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, & tranquilizers may increase 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
- 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 (1-800-222-1222). Quick medical attention is critical for adults & 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 & children 12 yrs & over	2 capsules with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

**when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing**

***Other information***

- store at room temperature

***Inactive ingredients***

D&C Yellow No. 10, gelatin, glycerin, Neelicert FD&C Blue No. 1, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide

***Questions or comments?***

call 1-855-274-4122

**Distributed by:**

**Pharmacy Value Alliance, LLC**

**407 East Lancaster Avenue,**

**Wayne, Pa 19087**

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 16 Capsules Bottle**

**NDC 68016-878-16**

**Premier Value®**

**COMPARE TO THE ACTIVE INGREDIENTS  
IN VICKS® NYQUIL® COLD & FLU  
NIGHTTIME RELIEF LIQUICAPS®**

**Multi-Symptom**

**Nighttime**

**COLD & FLU RELIEF**

**Acetaminophen, Dextromethorphan HBr and**

**Doxylamine Succinate Capsules**

**325 mg/15 mg/6.25 mg**

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

**16 Capsules**

LEBG9070

**Drug Facts**

**Active ingredients (in each capsule)**      **Purpose**  
Acetaminophen USP 325 mg.....Pain reliever/fever reducer  
Dextromethorphan HBr USP 15 mg.....Cough suppressant  
Doxylamine succinate USP 6.25 mg.....Antihistamine

**Uses** temporarily relieves common cold/flu symptoms:  
■ cough due to minor throat & bronchial irritation ■ sore throat ■ headache ■ minor aches & pains ■ fever ■ runny nose & sneezing

**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses in 24 hrs, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks daily 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.

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**Ask a doctor before use if you have** ■ liver disease ■ glaucoma ■ cough that occurs with too much phlegm (mucus)

**Drug Facts (continued)**

■ a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema ■ trouble urinating due to enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

**When using this product** ■ do not use more than directed ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, & tranquilizers may increase 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 ■ 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 (1-800-222-1222). Quick medical attention is critical for adults & 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 hrs  
adults & children 12 yrs & over      2 capsules with water every 6 hrs  
children 4 to under 12 yrs      ask a doctor  
children under 4 yrs      do not use

**Drug Facts (continued)**

■ when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

**Other information** ■ store at room temperature

**Inactive ingredients** D&C Yellow No. 10, gelatin

**Drug Facts (continued)**

glycerin, Neelcerb FD&C Blue No. 1, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide

**Questions or comments?** call 1-855-274-4122

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EXP.



**Multi-Symptom  
Nighttime  
COLD & FLU RELIEF**

**Acetaminophen, Dextromethorphan HBr,  
Doxylamine Succinate Capsules  
325 mg/15 mg/6.25 mg**

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

16 Capsules

NDC 68016-878-16

**\*COMPARE TO THE ACTIVE  
INGREDIENTS IN VICKS® NYQUIL®  
COLD & FLU NIGHTTIME RELIEF  
LIQUICAPS®**



**Multi-Symptom  
Nighttime  
COLD & FLU RELIEF**



Distributed By:  
Pharmacy Value Alliance, LLC  
407 East Lancaster Avenue,  
Wayne, Pa 19087  
If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Failure to follow these warnings could result in serious consequences.  
**KEEP OUTER CARTON FOR COMPLETE PRODUCT INFORMATION**

**TAMPER EVIDENT**  
Do not use if package is opened or if blister unit is torn, broken, or shows any signs of Tampering.

\*This product is not manufactured or distributed by Procter & Gamble, distributor of VICKS® NyQuil® Cold & Flu Nighttime Relief LiquiCaps®.

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# NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr and doxylamine succinate capsule

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-878
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: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	GREEN	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	Q07
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-878-16	8 in 1 CARTON	07/12/2019	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68016-878-24	12 in 1 CARTON	07/12/2019	
2		2 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	07/12/2019	

**Labeler** - Chain Drug Consortium, LLC (101668460)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	MANUFACTURE(68016-878)

Revised: 12/2020

Chain Drug Consortium, LLC