# COLD AND FLU NIGHTTIME/MULTI-SYMPTOM- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled Walgreen 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.

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#### Walgreens 44-660

#### Active ingredients (in each liquid-filled capsule)

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
  - minor aches and pains
  - fever
  - headache
  - 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

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 for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do not use

 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.

- if you have ever had an allergic reaction to this product or any of its ingredients
- to make a child sleepy
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

# Ask a doctor before use if you have

- liver disease
- glaucoma
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland

#### 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 beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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.

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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
- do not take more than 8 capsules per 24 hours
- adults and children 12 years and over: take 2 capsules with water every 6 hours
- children under 12 years : ask a doctor

# Other information

- protect from heat, humidity and light
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS

#### TORN OR BROKEN

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

#### **Inactive ingredients**

D&C yellow #10, edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol

Questions or comments?

1-800-426-9391

Principal Display Panel

Walgreens

Compare to Vicks<sup>®</sup> NyQuil<sup>®</sup> Cold & Flu LiquiCaps<sup>®</sup> active ingredients<sup>††</sup>

NDC 0363-6600-08

NIGHTTIME Cold & Flu

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER DEXTROMETHORPHAN HBr - COUGH SUPPRESSANT DOXYLAMINE SUCCINATE/ ANTIHISTAMINE

MULTI-SYMPTOM

• Relieves aches, fever, sore throat, sneezing, runny nose & cough

# 24

LIQUID CAPS ACTUAL SIZE

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

Walgreens Pharmacist Recommended Walgreens Pharmacist Survey

<sup>++</sup>This product is not manufactured or distributed by The Procter & Gamble Company, owner of the registered trademark Vicks<sup>®</sup> NyQuil<sup>®</sup> Cold & Flu LiquiCaps<sup>®</sup>.

50844 REV0418B66008

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015 Walgreens\_\_\_\_\_ 100% SATISFACTION \_\_\_\_\_\_GUARANTEED

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Walgreens 44-660

# COLD AND FLU NIGHTTIME/MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Informat							
Product Type		HUMAN OTC DRUG	Item Code (S	Item Code (Source)		NDC:0363-6600	
Route of Administra	tion	ORAL					
Active Ingredient							
Ingredient Name Basis of					rength	Strengt	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPH						325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9KYH)DEXTROMETHORPHAN(DEXTROMETHORPHAN - UNII:7355X3ROTS)HYDROBROMIDE					HAN	15 mg	
DO XYLAMINE SUCCI	NATE (UNII: V9	BI9B5YI2) (DOXYLAMINE - U	NII:95QB77JKPL)	DOXYLAMINE SUC	CINATE	6.25 mg	
Inactive Inquedie							
Inactive Ingredie	nts	Ingredient Name			St	rength	
D&C YELLOW NO. 10	) (UNII: 35SW5U	•				U	
FD&C BLUE NO. 1 (UI	NII: H3R47K3TB	D)					
GELATIN (UNII: 2G860	QN327L)						
GLYCERIN (UNII: PDC	6A3C0OX)						
POLYETHYLENE GLY	YCOL, UNSPEC	CIFIED (UNII: 3WJQ0SDW1A)					
POVIDONE (UNII: FZ9	89GH94E)						
PROPYLENE GLYCO	L (UNII) 6DC90	16 71/2)					
		(10/ V3)					
		(10/ V3)					
WATER (UNII: 059QF0	KO0R)	[10/ V3]					
WATER (UNII: 059QF0	KO0R)	[10/V3]					
WATER (UNII: 059QF0 SORBITOL (UNII: 506	KO0R) T60A25R)						
WATER (UNII: 059QF0 SORBITOL (UNII: 506	KO0R) T60A25R)		Score		no score		
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WATER (UNII: 059QF0 SORBITOL (UNII: 506 Product Characte	KOOR) T60A25R) eristics GREEN (c	lear) 5					
WATER (UNII: 059QF0 SORBITOL (UNII: 506 Product Characte Color Shape Flavor	KOOR) T60A25R) eristics GREEN (c	lear) 5	Size		21mm		
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WATER (UNII: 059QF0 SORBITOL (UNII: 506 Product Characte Color Shape Flavor Contains Packaging	KOOR) T60A25R) eristics GREEN (c	lear) 5	Size mprint Code	rketing Start Date	21mm 660	; End Dat	
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	0 3/0 1/20 15	

# Labeler - Walgreen Company (008965063)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
LNK International, Inc.		832867837	PACK(0363-6600)				

Revised: 8/2019

Walgreen Company