NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled Lil' Drug Store Products, 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 & Flu

Drug Facts

Active ingredients (in each softgel)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	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 daily 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

- 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 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, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or comments?

call toll-free **1-877-507-6516** (M-F 8AM-4:30PM CST)

Distributed by: Lil' Drug Store Products, Inc. 9300 Earhart Lane SW Cedar Rapids, IA 52404

PRINCIPAL DISPLAY PANEL - 16 Softgel Blister Pack Carton

QUALITY

⋆ GUARANTEED ⋆

Compare to the Active Ingredients in Vicks® NyQuil® LiquiCaps®**

Cold & Flu

Nighttime

Acetaminophen, Dextromethorphan HBr, and Doxylamine Succinate Pain Reliever/Fever Reducer, Cough Suppressant, Antihistamine

Relieves

- Sneezing Runny Nose
- Cough Aches
- Fever Sore Throat

ACTUAL SIZE

16 Softgels

Lil' DrugStore [®]

Cold & Flu Nighttime

Drug Facts (continued)

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**This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, NyQuil® and LiquiCaps® are registered trademarks of The Procter & Gamble Company.

> PARENTS: www.StopMedicineAbuse.org

Compare to the Active Ingredients in Vicks® NyQuil® LiquiCaps®**

Cold & Flu ighttime

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Relieves

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16 Softgels



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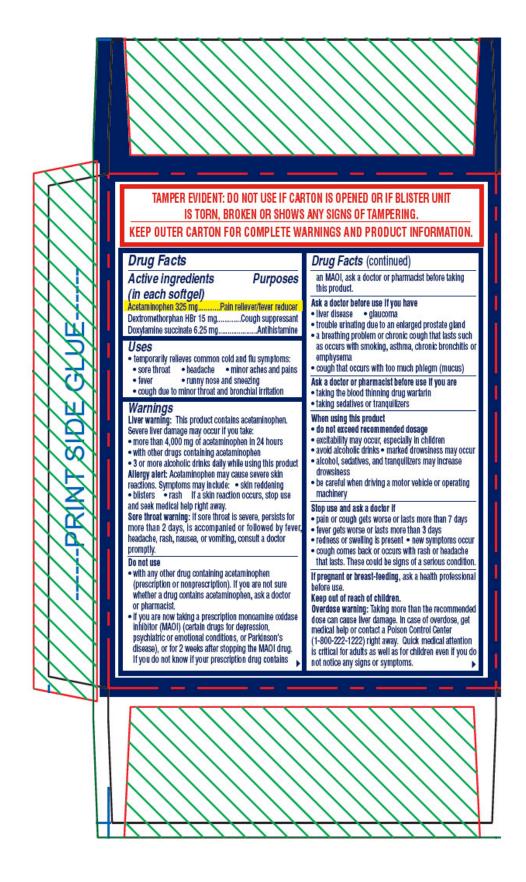
Distributed by: Lil' Drug Store Products, Inc. 9300 Earhart Lane SW Cedar Rapids, IA 52404

PLD-A569B FC006104

Lot No: Exp Date: Softgels are liquid-filled capsules.



Dextromethorphan HBr, and Doxylamine Succinate ain Reliever/Fever Reducer, Cough Suppressant, Antihistamine



NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and doxylamine succinate capsule, liquid filled

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:66715-6716

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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: H3R47K3TBD)		
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
MANNITOL (UNII: 30WL53L36A)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	P30
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715- 6716-8	8 in 1 CARTON	02/15/2020	
1		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	09/05/2014	

Labeler - Lil' Drug Store Products, Inc. (093103646)

Revised: 10/2022 Lil' Drug Store Products, Inc.