# COLD AND FLU NIGHTTIME SEVERE- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated 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.

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#### 24/7 Life Cold & Flu Nighttime Severe- (7-Eleven)

#### **Drug Facts**

#### **Active Ingredients (in each tablet)**

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

#### **Purpose**

Pain reliever/fever reducer Cough suppressant Antihistamine Nasal decongestant

#### Uses

- temporarily relieves common cold and flu symptoms:
- minor aches and pains
- sinus congestion and pressure
- sore throat
- fever
- headache
- nasal congestion
- cough due to minor throat and bronchial irritation
- runny nose and sneezing
- reduces swelling of nasal passages
- promotes nasal and/or sinus drainage
- temporarily restores freer breathing through the nose

#### **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:

- blisters
- rash
- skin reddening

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.
- 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
- diabetes
- thyroid disease
- heart disease
- glaucoma
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- 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)

## 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 exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic beverages
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

#### Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, 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 caplets in 24 hours
- adults and children 12 years and over: take 2 caplets with water every 4 hours
- children under 12 years: ask a doctor

#### Other Information

each caplet contains: sodium 3 mg 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**

black iron oxide, corn starch, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #1 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

#### **Questions or Comments?**

1-800-351-2000 (8:30 AM - 5:00 PM CST)

#### Satisfaction Guaranteed 1-800-255-0711

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Distributed by: 7-Eleven, Inc., Irving, TX 75063 www.7-ELEVEN.com

#### **6 Count Carton**

24/7 Life by 7-Eleven

Cold & Flu Nighttime Severe

#### Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr / Cough Suppressant Doxylamine Succinate / Antihistamine Phenylephrine HCl / Nasal Decongestant

**Relieves:** Headache, Fever, Sore Throat, Minor Aches & Pains, Nasal Congestion, Sinus Pressure, Sneezing, Runny Nose, Cough

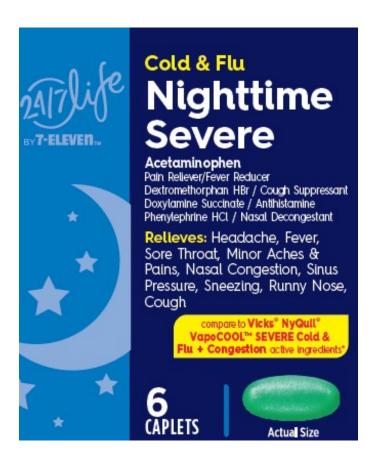
compare to V icks® NyQuil® VapoCOOL™ SEVERE Cold & Flu + Congestion active ingredients\*

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**CAPLETS** 

[caplet image]

**Actual Size** 



#### **COLD AND FLU NIGHTTIME SEVERE**

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-5053
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
TALC (UNII: 7SEV7J4R1U)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CROSPOVIDONE (UNII: 2S7830E561)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics				
Color	green	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	44;677	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:29485- 5053-6	6 in 1 CARTON	10/27/2021			
1		6 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	M012	10/27/2021	

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

Revised: 7/2023 Lil' Drug Store Products, Inc.