

NYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU- acetaminophen, phenylephrine hydrochloride, doxylamine succinate, and dextromethorphan hydrobromide tablet, 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.

NyQuil™ Severe+ VapoCOOL™ Cold & Flu

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 caplets in 24 hours, which is the maximum daily amount for this product

- 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

- 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- 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 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

- take only as directed
- do not exceed 8 caplets per 24 hrs

adults & children 12 yrs & over	2 caplets with water every 4 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- do not exceed 25°C

Inactive ingredients

crospovidone, D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions?

1-800-362-1683

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

PRINCIPAL DISPLAY PANEL - 4 Caplet Pouch Carton

NyQuil™

SEVERE+

VICKS[®] VapoCOOL[™]

COLD & FLU

Acetaminophen, Phenylephrine HCl,
Doxylamine Succinate, Dextromethorphan HBr

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure
- Sneezing, Runny Nose
- Cough

Nighttime Relief

4

Coated Caplets

Lil'

DrugStore[®]

NyQuil SEVERE+



COLD & FLU

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Nighttime Relief

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Coated Caplets



PARENTS:
Learn about how medicine works
www.StuffKiddzKnow.com

NyQuil SEVERE+
Vicks VapoCOOL
COLD & FLU

DO NOT USE IF THE POUCH IS BROKEN OR TORN.

FAILURE TO FOLLOW THESE WARNINGS COULD RESULT IN SERIOUS CONSEQUENCES.

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LIFT PANEL FOR CONTINUED DRUG FACTS

Drug Facts (continued)

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4 Coated
Caplets

VapoCOOL
COLD & FLU



VapoCOOL
SEVERE+

NyQuil

Drug Facts (continued)

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Questions? 1-800-362-1683

Manufactured for Procter & Gamble, Cincinnati, OH 45202

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Lil' Drug Store Products, Inc., 9300 Earhart Lane SW, Cedar Rapids, IA 52404
1-877-507-6516 (M-F 8AM-4:30PM CT) 97052C-US-06-18-A



NYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU

acetaminophen, phenylephrine hydrochloride, doxylamine succinate, and dextromethorphan hydrobromide tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-9905
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
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Shape	OVAL	Size	19mm
Flavor		Imprint Code	NQ
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-9905-2	2 in 1 CARTON	05/01/2019	
1		2 in 1 POUCH; 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	05/01/2019	

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

Revised: 10/2022

Lil' Drug Store Products, Inc.