DAYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine 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.

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Drug Fatcs

Active Ingredient in each caplet

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/Fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial

passageways of bothersome mucus and make coughs more productive.

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
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

When using this product, do not use more than directed.

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 4 doses 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

- each caplet contains: sodium 4 mg
- do not exceed 25°C

Inactive Ingredients

croscarmellose sodium, crospovidone, FD&C Yellow No. 6 Aluminum Lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, sucralose, talc, titanium dioxide

Questions?

1-800-362-1683

Manufactured for Procter & Gamble, Cincinnati, OH 45202 www.vicks.com Patents: www.pg.com/patents

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CVP 4 Caplet Pouch Carton

DayQuil ™

SEVERE+

VICKS® VapoCOOL™

COLD & FLU

Acetaminophen, Phenylephrine HCl,

Dextromethorphan HBr, Guaifenesin

Minor Aches & Pains, Fever Nasal/Sinus Congestion & Sinus Pressure Cough Chest Congestion

[caplet image]

Non-Drowsy

4

Coated Caplets

CVP

HEALTH



DAYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29485-6580
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		

Inactive Ingredients			
Ingredient Name	Strength		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	DQ	
Contains				

P	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:29485- 6580-4	4 in 1 CARTON	08/25/2017	11/23/2025		
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	M012	08/25/2017	11/23/2025

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

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