DAYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU, CVP HEALTHacetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated DAYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU, TRAVEL BASIXacetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated DAYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride 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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# DayQuil<sup>™</sup> Severe+ VapoCOOL<sup>™</sup> Cold & Flu

## Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/Fever
	reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
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
- 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 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 8 caplets per 24 hrs

adults & children 12	2 caplets with water
yrs & over	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

**Product repackaged and distributed with permission of manufacturer by:** Lil' Drug Store Products, Inc., 9300 Earhart Lane SW, Cedar Rapids, IA 52404

# **PRINCIPAL DISPLAY PANEL - 6 Caplet Pouch Carton**

DayQuil™ SEVERE+ VICKS<sup>®</sup> VapoCOOL™

COLD & FLU

Acetaminophen, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

- Minor Aches & Pains, Fever
- Nasal Congestion & Sinus Pressure

- CoughChest Congestion

Non-Drowsy

6 Coated Caplets

Liľ Drug Store ®





DayQuil Severe + VapoCOOL Cold & Flu, Travel BASIX PDP/Package

DayQuil™

SEVERE+ VICKS <sup>®</sup> VapoCOOL<sup>™</sup>

# COLD & FLU

**Acetaminophen**, Phenylephrine HCl, Dextromethorphan HBr, Guaifenesin

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

## **Non-Drowsy**

# [caplet image]

#### 4

**Coated Caplets** 

[Travel BASIX logo]



DayQuil™ SEVERE+ VapoCOOL™ Cpld & Flu , CVP HEALTH - PDP/Package

DayQuil™

SEVERE+

VICKS <sup>®</sup> VapoCOOL<sup>™</sup>

COLD & FLU

Acetaminophen, Phenylephrine HCl,

Dextromethorphan HBr, Guaifenesin

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

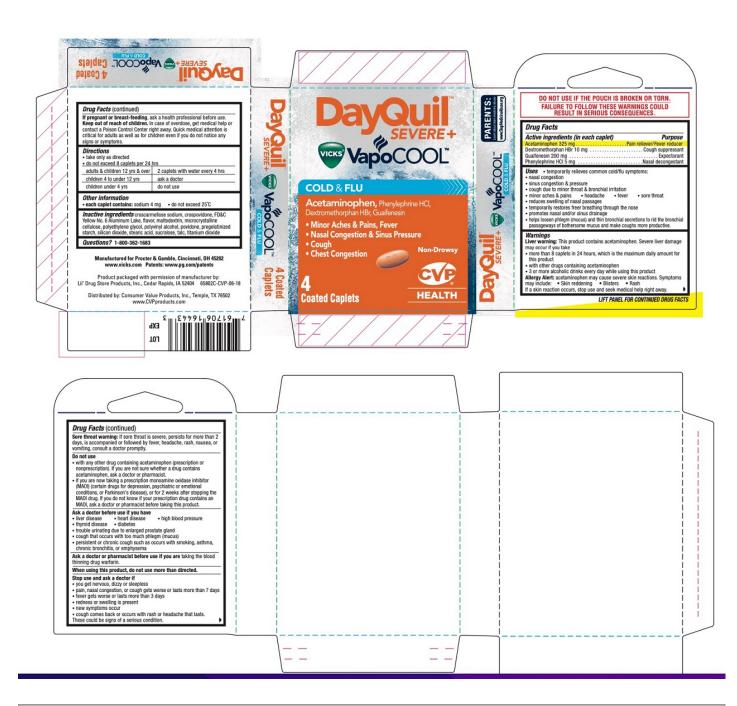
[caplet image]

#### **Non-Drowsy**

### 4

Coated Caplets

 $[\mathsf{CVP}_{\ \mathbb{R}} \text{ HEALTH logo}]$ 



# DAYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU, CVP HEALTH

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

Product Information					
Product Type	HUMAN OTC DRUG	ltem Code (S	Source)	NDC:6671	5-6580
Route of Administration	ORAL				
Active Ingredient/Active	Moiety				
	<b>Moiety</b> dient Name		Basis of St	rength	Strength
Active Ingredient/Active Ingre ACETAMINOPHEN (UNII: 362091T	dient Name	III:362O9ITL9D)	Basis of St ACETAMINOPHEN	•	<b>Strength</b> 325 mg

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W745	1VQ) GUAIFENES IN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYL UNII:1WS297W6MV)	EPHRINE - PHENYLEPHRINE HYDROCHLORIDE	5 mg
Inactive Ingredients		
Ingredient Name		Strength
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
STARCH, CORN (UNII: 08232NY3SJ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		

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

### Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:66715- 6580-2	2 in 1 CARTON	08/01/2022	
	2 in 1 POUCH; Type 0: Not a Combination Product		
Marketing I			
Marketing I Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

# DAYQUIL SEVERE PLUS VAPOCOOL COLD AND FLU, TRAVEL BASIX

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

Product Type		HUMAN OTC DRUG	Item Code (	Source)	NDC:6671	.5-6404
Route of Admini	stration	ORAL				
	Stration					
Active Ingredi	ent/Active	Moiety				
	Ingree	dient Name		Basis of St	trength	Strengt
ACETAMINOPHEN	(UNII: 36209ITL	9D) (ACETAMINOPHEN	- UNII:362O9ITL9D)	ACETAMINOPHEN	J	325 mg
DEXTROMETHORP		ROMIDE (UNII: 9D2RTI (3ROTS)	9КҮН)	DEXTROMETHOR HYDROBROMIDE	PHAN	10 mg
GUAIFENESIN (UNII	: 495W7451VQ	) (GUAIFENES IN - UNII:4	95W7451VQ)	GUAIFENESIN		200 mg
PHENYLEPHRINE H JNII:1WS297W6MV)	IYDROCHLORI	<b>DE</b> (UNII: 04JA59TNSJ)	(PHENYLEPHRINE -	PHENYLEPHRINE HYDROCHLORIDE	<u>:</u>	5 mg
nactive Ingre	dients					
		Ingredient Na	ne		S	trength
TALC (UNII: 7SEV7J4	IR1U)					
TITANIUM DIOXIDE	<b>(</b> UNII: 15FIX9V	(2JP)				
ROSCARMELLOS	E SODIUM (UN	II: M28OL1HH48)				
ROSPOVIDONE (1	L5 MPA.S AT 5	<b>5%)</b> (UNII: 68401960Mk	()			
D&C YELLOW NO	.6 (UNII: H77∨	(EI93A8)				
MALTODEXTRIN (U	NII: 7CVR7L4A2	D)				
		E (UNII: OP1R32D61U)				
		CIFIED (UNII: 3WJQ0S				
		FIED (UNII: 532B59J99	0)			
POVIDONE, UNSPE						
STARCH, CORN (UI		•				
		)				
SUCRALOSE (UNII:	90000032.04)					
Product Chara	cteristics					
Color	ora	nge Scor	e		no score	
Shape	OVA	Size			19mm	
Flavor		Impr	int Code		DQ	
Contains						
Packaging						
# Item Code	Рас	kage Description	Mark	eting Start Date		ting End ate
NDC:66715- 6404-2	2 in 1 CARTON	N	11/28/20	22		
1	2 in 1 POUCH; Product	; Type 0: Not a Combir	ation			

Marketing Category	Applica	tion Number o Citation		graph	Ма	rketing Start Date		eting End Date
OTC monograph final	M012			-	11/28	/2022		
					A NI			
DAYQUIL SEV							udua a la cualua	a ala la vial a
acetaminophen, de	xtrometho	orphan nyarobi	romiae,	guairenes	sin, a	ana pnenylepn	irine nyar	ochioride
ablet, coated								
Product Informa	ation							
Product Type		HUMAN OTC DRU	JG	Item Coo	de (S	ource)	NDC:6671	5-9904
Route of Administ	ration	ORAL						
Active Ingredien		-						
	-	dient Name				Basis of St	-	Strength
					.9D)	ACETAMINOPHEN		325 mg
<b>DEXTROMETHORPHA</b> (DEXTROMETHORPHAN			J2RTI9KYF	1)		DEXTROMETHORI HYDROBROMIDE	PHAN	10 mg
GUAIFENESIN (UNII: 4	95W7451VQ)	(GUAIFENESIN -	UNII:495W	Π451VQ)		GUAIFENESIN		200 mg
PHENYLEPHRINE HYD	DROCHLORI	<b>DE</b> (UNII: 04JA59T	rnsj) (phe	NYLEPHRIN	E -	PHENYLEPHRINE		5 mg
UNII:1WS297W6MV)						HYDROCHLORIDE		59
Inactive Ingredi	ents							
J		Ingredient	Name				S	trength
CROSCARMELLOSE S	ODIUM (UN	- II: M28OL1HH48)						-
<b>CROSPOVIDONE (15</b>	MPA.S AT 5	<b>%)</b> (UNII: 684019	960MK)					
FD&C YELLOW NO. 6	6 (UNII: H77V	EI93A8)						
MALTODEXTRIN (UNII		•						
MICROCRYSTALLINE	CELLULOSI	(UNII: OP1R32D	61U)					
POLYETHYLENE GLYC			-	A)				
POLYVINYL ALCOHOL			59J990)					
POVIDONE, UNSPECI								
STARCH, CORN (UNII:		•						
SILICON DIOXIDE (UN	III: ETJ7Z6XB	U4)						
STEARIC ACID (UNII: 4	ELV7Z65AP							
SUCRALOSE (UNII: 96	<6UQ3ZD4)							
TALC (UNII: 7SEV7J4R1								
TITANIUM DIOXIDE (U	JNII: 15FIX9V	2JP)						
Product Charact	teristics							
Color	orai	nge	Score				no score	
Shape	OVA	-	Size				19mm	
•	0.11			Code				
Flavor Imprint Code DQ								

Contains

Pa	ackaging					
#	ltem Code	Package Description	ſ	Marketing Start Date	I	Marketing End Date
L	NDC:66715- 9904-2	2 in 1 CARTON	05/	01/2019		
1		2 in 1 POUCH; Type 0: Not a Combination Product				
2	NDC:66715- 9904-3	3 in 1 CARTON	05/	01/2019	03/	29/2025
2		2 in 1 POUCH; Type 0: Not a Combination Product				
3	NDC:66715- 9904-7	20 in 1 CARTON	05/	01/2019	05/31/2024	
3		2 in 1 POUCH; Type 0: Not a Combination Product				
Μ	larketing l	nformation				
	Marketing Category	Application Number or Monograpl Citation	h	Marketing Start Date		Marketing End Date
דר	C monograph final	M012		05/01/2019		

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

Revised: 9/2023

Lil' Drug Store Products, Inc.