DAYTIME COLD AND FLU NON DROWSY- acetaminohpen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled P & L Development, LLC

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethoprhan HBr 10 mg

Phenlyephrine HCL 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves common cold and flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - fever
 - 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 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
- diabetes
- heart disease
- thyroid disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, 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.

When using this product,

do not exceed recommended dosage.

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- nervousness, dizziness, or sleeplessness occur
- 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 4 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 insure correct dosing

Other information

- store between 15-30°C (59-86°F)
- avoid excessive heat

Inactive ingredients

butylated hydroxyanisole, butylated hydroxytoluene, FD&C yellow#6, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to active ingredients in Vicks® DayQuil® Cold & Flu LiquiCaps®†

non-drowsy

multi-symptom

daytime cold & flu relief

- Acetaminophen 325 mg pain reliever / fever reducer
- dextromethorphan HBr 10 mg cough suppressant
- phenylephrine HCL 5 mg nasal decongestant

alcohol-free

antihistamine-free

softgels**

(**liquid-filled capsules)

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

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWING ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by: **PL Developments**

200 Hicks Street, Westbury, NY 11590

Package Label

thinning drug warfarin.

Ask a doctor or pharmacist before use if you are taking the blood

- condy that occurs with too much phiegm (mucus)
- bersistent or chronic cough such as occurs with smoking, asthma, or ■ trouble unnating due to an enlarged prostate gland
- µiôµ piooq bressure ■ heart disease ■ thyroid disease Ask a doctor before use if you have Satadsid III ■ liver disease

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Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms

- 3 or more alcoholic drinks every day while using this product
 - with other drugs containing acetaminophen
 - more than 4,000 mg of acetaminophen in 24 hours may occur if you take:

Liver warning: This product contains acetaminophen. Severe liver damage *SbuuueM*

nund races (continued)

C9II 1-811-123-3932 Woudey-Friday 9AM-5PM EST Unestions or comments?

glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink hydroxytoluene, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene Inactive ingredients butylated hydroxyanisole, butylated

> ■ store between 15-30°C (59-86°F)
> ■ avoid excessive heat Other information

> > label to ensure correct dosing

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 - swsllow whole; do not crush, chew, or dissolve
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If pregnant or breast-feeding, ask a health professional before use.

These could be signs of a serious condition.

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 - redness or swelling is present
 new symptoms occur ■ Tever gets worse or lasts more than 3 days

 - uervousness, dizziness, or sleeplessness occur
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Ound Facts (continued)

Nasal decongestant Рћепујерћипе НСІ 5 тд. Cough suppressant Dextromethorphan HBr 10 mg. AID TRIIEVET/TEVET FEDUCET Acetaminophen 325 mg

Active ingredients (in each softgel) Səsoding

Drug Facts

 cough due to minor throat and bronchial irritation ■ ussal congestion ■ fever ■ headache ■ sore throat ■ winor aches and pains **NSGS** I semporarily relieves common cold and flu symptoms:

Orug Facts (continued)

Compare to active ingredients in Vicks® DayQuil® Cold & Flu LiquiCaps®t

NDC 59726-848-08

non-drowsy multi-symptom

cold & flu relief

 Acetaminophen 325 mg pain reliever/fever reducer

- dextromethorphan HBr 10 mg cough suppressant
- phenylephrine HCl 5 mg nasal decongestant

alcohol-free antihistamine-free



actual size

EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

8 softaels*









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Distributed by: **PL Developments** 200 Hicks Street, Westbury, NY 11590





READYinCASE Daytime Cold & Flu Relief

DAYTIME COLD AND FLU NON DROWSY

acetaminohpen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:59726-848

Route of Administration ORAL

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

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics				
Color	orange	Score	no score	
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	P19	
Contains				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:59726-848- 08	8 in 1 CARTON	06/30/2019	06/30/2025		
1		1 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 Drug	M012	06/30/2019	06/30/2025		

Labeler - P & L Development, LLC (800014821)

Revised: 4/2024 P & L Development, LLC