

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

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**Drug Facts**

**Active ingredients (in each softgel)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 10 mg

Phenylephrine 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 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

FD&C yellow #6, FD&C red #40, gelatin, glycerin, lecithin, light mineral oil, 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)

Softgels\*\*

(\*\*liquid-filled capsules)

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**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**



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

alcohol-free  
antihistamine-free

16 softaels™

Compare to the active ingredients in  
Vicks® DayQuil® Cold & Flu LiquiCaps<sup>†</sup>  
NDC 59726-898-16  
non-drowsy  
multi-symptom  
**day time**  
cold & flu relief

actual size



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KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

t No.:  
p. Date:

<p><b>Drug Facts (continued)</b></p> <p><b>Uses</b> ■ 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</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each softgel)</b> Acetaminophen 325 mg.....Pain reliever/fever reducer Dextromethorphan HBr 10 mg.....Cough suppressant Phenylephrine HCl 5 mg.....Nasal decongestant</p>
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<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b> ■ 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.</p> <p><b>Keep out of reach of children.</b> <b>Overdose warning:</b> 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.</p> <p><b>Directions</b> ■ 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</p> <p><b>Other information</b> ■ store between 15-30°C (59-86°F) ■ avoid excessive heat</p> <p><b>Inactive ingredients</b> FD&amp;C yellow #6, FD&amp;C red #40, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink</p> <p><b>Questions or comments?</b> Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Warnings</b> 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</p> <p><b>Allergy alert:</b> 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.</p> <p><b>Sore throat warning:</b> 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.</p> <p><b>Do not use</b> ■ 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.</p> <p><b>Ask a doctor before use if you have</b> ■ 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</p> <p>■ cough that occurs with too much phlegm (mucus)</p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b></p> <p><b>When using this product, do not exceed recommended dosage.</b></p>
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(\*\*liquid-filled capsules)

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**PL Developments**  
200 Hicks Street  
Westbury, NY 11590



### READYinCASE Day Time Cold and Flu Relief

## DAYTIME COLD AND FLU NON DROWSY

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59726-898
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm

<b>Flavor</b>		<b>Imprint Code</b>	PC9
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59726-898-08	8 in 1 CARTON	10/30/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:59726-898-16	16 in 1 CARTON	10/30/2019	
2		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	10/30/2019	

**Labeler** - P & L Development, LLC (800014821)