

**DAYTIME COLD AND FLU NON DROWSY- acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled  
Cardinal Health (Leader) 70000**

*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 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**

butylated hydroxyanisole\*, butylated hydroxytoluene\*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol\*, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide\*, white ink

\*contains one or more of these ingredients

### **Questions or comments?**

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

### **Principal Display Panel**

COMPARE TO VICKS® DAYQUIL® COLD & FLU LIQUICAPS® active ingredients†

Daytime | Multi-Symptom

### **Cold & Flu Relief**

**Acetaminophen** | Dextromethorphan HBr | Phenylephrine HCl

Pain Reliever / Fever Reducer | Cough Suppressant | Nasal Decongestant

Relieves:

Aches, Fever, Sore Throat

Cough, Nasal Congestion

Non-Drowsy

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 CARDINAL HEALTH

DUBLIN, OHIO 43017

[www.myleader.com](http://www.myleader.com) 1-800-200-6313

**Package Label**

NDC 70000-0463-1

LEADER™

Daytime | Multi-Symptom

# Cold & Flu Relief

Acetaminophen | Dextromethorphan HBr | Phenylephrine HCl  
Pain Reliever / Fever Reducer | Cough Suppressant | Nasal Decongestant

Relieves:  
Aches, Fever, Sore Throat  
Cough, Nasal Congestion

Non-Drowsy

24 SOFTGELS\*\*  
\*\*Liquid-Filled Capsules



Actual Size

COMPARE TO  
VICKS® DAYQUIL®  
COLD & FLU  
LIQUICAPS®  
active ingredients†

100% Money  
Back Guarantee

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Lot No.:  
Exp. Date:

### Drug Facts (continued)

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**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.**

### Drug Facts (continued)

**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 doses in 24 hours  
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### Other information

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**Inactive ingredients** butylated hydroxyanisole, butylated hydroxytoluene, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide, white ink

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### Purposes

■ 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

### Uses

Drug Facts (continued)

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CIN 5488689 REV. 12/18



PLD-A40R FC004958

## LEADER 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:70000-0463
<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>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<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>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

#### 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>	P19;95A;AP016

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0463-1	24 in 1 CARTON	12/31/2018	12/27/2024
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 final	part341	12/31/2018	12/27/2024

**Labeler** - Cardinal Health (Leader) 70000 (063997360)

Revised: 9/2022

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