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

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#### **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**

FD&C red #40, FD&C yellow#6, 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**

 ${\tt COMPARE\ TO\ VICKS@\ DAYQUIL@\ COLD\ \&\ FLU\ LIQUICAPS@\ active\ ingredients † }$ 

Daytime | Multi-Symptom

#### Cold & Flu Relief

Acetaminophen | Dextromethorphan HBr | Phenylephrine HCI

Pain Reliever / Fever Reducer | Cough Suppressant | Nasal Decongestant

Relieves:

Aches, Fever, Sore Throat

Cough, Nasal Congestion

Non-Drowsy

SOFTGELS\*\*

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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 1-800-200-6313

#### **Package Label**

LEADER 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:70000-0515
Route of Administration	ORAL		

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

<sup>\*\*</sup>liquid-Filled Capsules

Inactive Ingredients		
Ingredient Name	Strength	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
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: 059QF0KOOR)		
SORBITAN (UNII: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
MANNITOL (UNII: 30WL53L36A)		

Product Characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	PC9
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70000-0515-1	24 in 1 CARTON	08/30/2019		
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	08/30/2019	

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

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