

**NIGHTTIME COLD AND FLU MULTI SYMPTOM- acetaminophen
dextromethorphan hydrobromide doxylamine succinate capsule, liquid filled
Cardinal Health (Leader) 70000**

Safeway Nighttime Cold & Flu

Active Ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine Succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

- temporarily relieves common cold and flu symptoms:
 - sore throat
 - headache
 - minor aches and pains
 - fever
 - runny nose and sneezing
 - 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough such as occurs with smoking, asthma, chronic bronchitis, 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
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- pain 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.

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 6 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

D&C yellow #10, FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol oil, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or Comments?

Call **1-877-753-3929** Monday-Friday 9AM-5PM EST

Principal Display Panel

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

Nighttime | Multi-Symptom

Cold & Flu Relief

Acetaminophen, Dextromethorphan HBr, Doxylamine Succinate

Pain Reliever / Fever Reducer | Cough Suppressant | Antihistamine

Relieves: Fever, Sore Throat, Cough, Runny Nose, Sneezing, Headache, Aches and Pains

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 SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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DUBLIN, OHIO 43017

www.myleader.com 1-800-200-6313

Package Label

NDC 70000-0516-2

Nighttime | Multi-Symptom

Cold & Flu Relief

Acetaminophen | Dextromethorphan HBr | Doxylamine Succinate
Pain Reliever / Fever Reducer | Cough Suppressant | Antihistamine

Relieves: Fever, Sore Throat,
Cough, Runny Nose, Sneezing,
Headache, Aches and Pains

24 SOFTGELS**
**Liquid-Filled Capsules



Actual Size

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

100% Money
Back Guarantee

LEADER™

UPPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BULSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

No.:
Date:

Drug Facts (continued)

Warnings This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 4,000 mg of acetaminophen in 24 hours ■ 3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash

Severe 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.

Ask a doctor before use if you have ■ liver disease ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis 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 ■ sedatives or tranquilizers

When using this product ■ do not exceed recommended dosage ■ excitability may occur, especially in children ■ avoid alcoholic drinks ■ marked drowsiness may occur

Drug Facts (continued)

Stop use and ask a doctor if ■ pain 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.** 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 6 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 ensure correct dosing

Other information ■ store between 15-30°C (59-86°F) ■ avoid excessive heat ■ inactive ingredients D&C yellow #10, FD&C blue #1, 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

Drug Facts

Active ingredients (in each softgel)

Doxylamine succinate 6.25 mg.....Antihistamine
Dextromethorphan HBr 15 mg.....Cough suppressant
Acetaminophen 325 mg.....Pain reliever/fever reducer

Purposes

Uses ■ temporarily relieves common cold and flu symptoms: ■ sore throat ■ headache ■ minor aches and pains ■ fever ■ runny nose and sneezing ■ cough due to minor throat and bronchial irritation

Drug Facts (continued)



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CIN 5564257 REV. 9/19



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PLD-B585B FC006107

LEADER Nighttime Cold & Flu Relief

NIGHTTIME COLD AND FLU MULTI SYMPTOM

acetaminophen dextromethorphan hydrobromide doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0516
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	21mm

Flavor			Imprint Code	PC10
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0516-1	16 in 1 CARTON	08/30/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000-0516-2	24 in 1 CARTON	08/30/2019	
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	08/30/2019	

Labeler - Cardinal Health (Leader) 70000 (063997360)