

**NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled**  
**PuraCap Pharmaceutical LLC**

*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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**NIGHTTIME COLD & FLU**

**Drug Facts**

**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/flu symptoms:

- cough due to minor throat & bronchial irritation
- sore throat
- headache
- minor aches & pains
- fever
- runny nose & sneezing

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

**Sore throat warning**

If sore throat is severe, lasts more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

**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.

### **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.
- to make a child sleep

### **Ask a doctor before use if you have**

- liver disease
- glaucoma
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to enlarged prostate gland

### **Ask a doctor or pharmacist before use if you are**

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

### **When using this product**

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

### **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 care professional before use.

**Keep out of reach of children.**

### **Overdose warning**

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

### **Directions**

- take only as directed - see Overdose warning
- do not exceed 4 doses per 24 hrs

|                                 |                                   |
|---------------------------------|-----------------------------------|
| adults & children 12 yrs & over | 2 softgels with water every 6 hrs |
| children 4 to under 12 yrs      | ask a doctor                      |
| children under 4 yrs            | do not use                        |

- **when using other Nighttime or Daytime products, carefully read each label to ensure correct dosing**

#### **Other information**

- store at room temperature 15°-30°C (59°-86°F)

#### **Inactive ingredients**

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

#### **Questions or comments?**

Call toll free: **1-855-215-8180**

#### **PRINCIPAL DISPLAY PANEL**

MARKET BASKET NIGHTTIME COLD & FLU LIQUID CAPS

20 SOFTGELS

NDC 51013-131-08

\*Compare to the active ingredients in VICKS® NyQuil® Cold & Flu

**NIGHTTIME  
COLD & FLU**

STORE AT ROOM TEMPERATURE  
AVOID EXCESSIVE HEAT

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

NDC 51013-131-08

MORE VALUE FOR YOUR DOLLAR

**MARKET BASKET**

**NIGHTTIME  
COLD & FLU**

**LIQUID CAPS**

**ACETAMINOPHEN,  
Dextromethorphan HBr,  
Doxylamine Succinate**

PAIN RELIEVER • FEVER REDUCER  
COUGH SUPPRESSANT • ANTIHISTAMINE

RELIEVES MAJOR COLD & FLU-LIKE  
SYMPTOMS SO YOU CAN REST.

**20 SOFTGELS**

SEE NEW WARNINGS INFORMATION



Distributed by:  
Demoulas Supermarkets Inc.  
875 East St.  
Tewksbury, MA 01876

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Made in China

LOT NO: \_\_\_\_\_

EXP DATE: \_\_\_\_\_

QUESTIONS OR COMMENTS? Call toll free 1-855-215-8188

Inactive ingredients

Other information

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Drug Facts (continued)

Warnings

Uses

Purpose

COATING FREE AREA

| <b>NIGHTTIME COLD AND FLU</b>   |                |                           |                |
|---|----------------|---------------------------|----------------|
| acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled |                |                           |                |
| Product Information   |                |                           |                |
| <b>Product Type</b>   | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:510 13-131 |
| <b>Route of Administration</b>  | 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)                            |          |
| SORBITOL (UNII: 506T60A25R)                         |          |

## Product Characteristics

|          |                  |              |          |
|----------|------------------|--------------|----------|
| Color    | green (clear)    | Score        | no score |
| Shape    | capsule (oblong) | Size         | 20mm     |
| Flavor   |                  | Imprint Code | PC10     |
| Contains |                  |              |          |

## Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:51013-131-08 | 2 in 1 CARTON   | 06/30/2016           |                    |
| 1 |                  | 10 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                                  | 06/30/2016           |                    |

**Labeler** - PuraCap Pharmaceutical LLC (962106329)

## Establishment

| Name   | Address | ID/FEI    | Business Operations                          |
|--|---------|-----------|--|
| Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd |         | 421293287 | manufacture(51013-131) , analysis(51013-131) |

