

## **NIGHT TIME- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled**

**H E B**

*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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### **HEB Night Time 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 and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

#### **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, lasts 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

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

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an 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**

- 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 professional before use.

### **Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as 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 hours

|                                 |                                   |
|---------------------------------|-----------------------------------|
| 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                        |

### **Other information**

- store at 20-25°C (68-77°F)

### **Inactive ingredients**

D&C yellow no. 10, edible ink\*, FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

### **Questions or comments?**

**1-800-719-9260**

### **Package/Label Principal Display Panel**

Compare to Vicks<sup>®</sup> NyQuil<sup>®</sup> Cold & Flu active ingredients

Nighttime

Acetaminophen / Pain Reliever/Fever Reducer

Dextromethorphan HBr / Cough Suppressant

Doxylamine Succinate / Antihistamine

Cold & Flu

Multi-Symptom

Relief of:

Pain - Fever - Cough

Sneezing - Runny Nose

actual size

24 SOFTGELS

# PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

MADE IN CANADA  
MADE WITH PRIDE & CARE FOR H-E-B®  
SAN ANTONIO, TX 78204

100%  
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promise

H-E-B®

If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

8580 - 1806



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Compare to Vicks® NyQuil® Cold & Flu active ingredients\*\*

NDC 37808-056-62

H-E-B®

# Nighttime

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

Cold & Flu

Multi-Symptom

Relief of:

- Pain • Fever • Cough
- Sneezing • Runny Nose



actual size

## 24 SOFTGELS

### CONVENIENT RECLOSEING TAB

\*\*This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil® Cold & Flu.

#### Drug Facts

**DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN**

| Active ingredients (in each softgel) | Purpose                     |
|--------------------------------------|-----------------------------|
| Acetaminophen 325 mg.....            | Pain reliever/fever reducer |
| Dextromethorphan HBr 15 mg.....      | Cough suppressant           |
| Doxylamine succinate 6.25 mg.....    | Antihistamine               |

**Uses:** temporarily relieves common cold/flu symptoms:

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

#### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

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- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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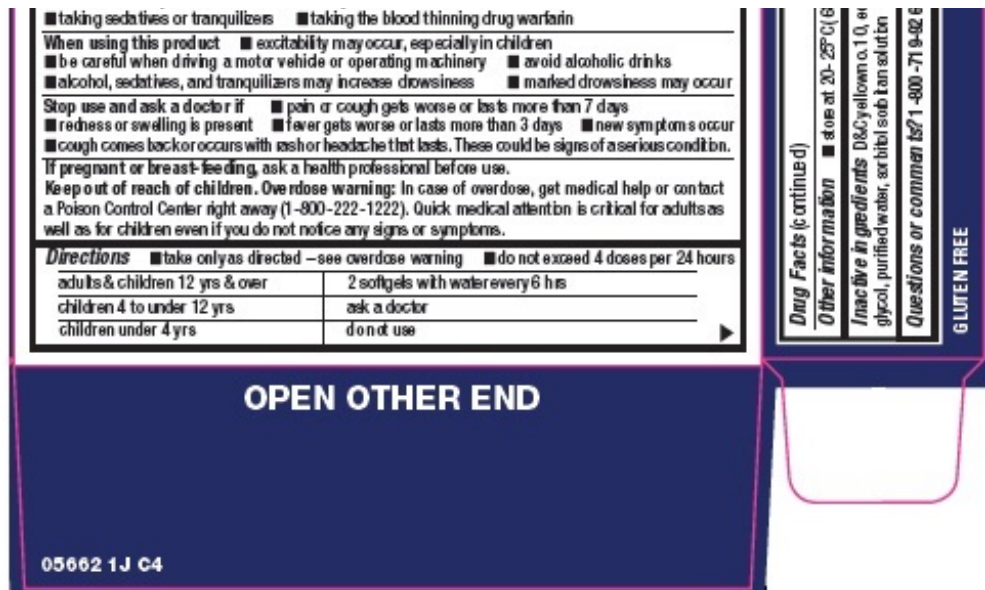
**Do not use** ■ with any other drug containing acetaminophen (prescription or nonprescription).  
 If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, 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. ■ if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if you have** ■ cough that occurs with too much phlegm (mucus)  
 ■ a breathing problem such as emphysema or chronic bronchitis ■ liver disease ■ glaucoma  
 ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema  
 ■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

8-77F)

dible ink\*, FD/Cib (ie. no. 1, gelatin, glycerin, polyethylene glycol, polydioxane, pepsylane  
\*may contain this ingredient



## NIGHT TIME

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:37808-056 |
| <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, UNSPECIFIED (UNII: 2G86QN327L)             |          |
| GLYCERIN (UNII: PDC6A3C0OX)                         |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)            |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                 |          |
| WATER (UNII: 059QF0K00R)                            |          |
| SORBITOL (UNII: 506T60A25R)                         |          |
| SORBITAN (UNII: 6O92ICV9RU)                         |          |

### Product Characteristics

|              |               |              |          |
|--------------|---------------|--------------|----------|
| <b>Color</b> | GREEN (clear) | <b>Score</b> | no score |
|--------------|---------------|--------------|----------|

|                 |      |                     |      |
|-----------------|------|---------------------|------|
| <b>Shape</b>    | OVAL | <b>Size</b>         | 20mm |
| <b>Flavor</b>   |      | <b>Imprint Code</b> | 056  |
| <b>Contains</b> |      |                     |      |

### Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:37808-056-62 | 12 in 1 CARTON   | 04/14/2014           |                    |
| 1 |                  | 2 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                                  | 04/14/2014           |                    |

**Labeler** - HEB (007924756)

Revised: 12/2019

HEB