# NIGHTTIME COLD AND FLU READYINCASE- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid P & L Development, LLC

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## **Drug Facts**

## Active ingredients (in each 30 mL)

## Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

### **Purposes**

#### Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

#### Uses

- temporarily relieves these common cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- 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 is followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do not use

- 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.
- with any other drug containing acetaminophen (prescription or non-prescription). 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
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

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

- sedatives or tranquilizers
- 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
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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 (overdose) may 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 any 24-hour peroid
- measure only with dosing cup provided. Do not use any other dosing device.
- mL= milliliter
- keep dosing cup with product
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years of age: do not use
- When using other Day Time or Night Time products, carefully read each label to insure correct dosing

#### Other information

- each 30 mL contains; potassium 5 mg
- each 30 mL contain sodium 19 mg
- store between 20-25°C (68-77°F). Do not refrigerate

## **Inactive ingredients**

acesulfame potassium, alcohol, citric acid, D&C yellow 10, FD&C green 3, FD&C yellow 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

## **Questions or Comments?**

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

## **Principal Display Panel**

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

## **Night Time**

#### Cold & Flu relief

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

pain reliever/fever reducer

cough suppressant

antihistamine

#### relieves:

- fever.
- headache

- sore throat
- cough
- minor aches and pains
- runny nose & sneezing

for ages 12 years & over

alcohol 10%

FL OZ (mL)

\*This product is not manufactured or distributed by The Procter & Gamble Company, Vicks® and NyQuil® are registered trademarks of The Procter & Gamble Company.

## TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

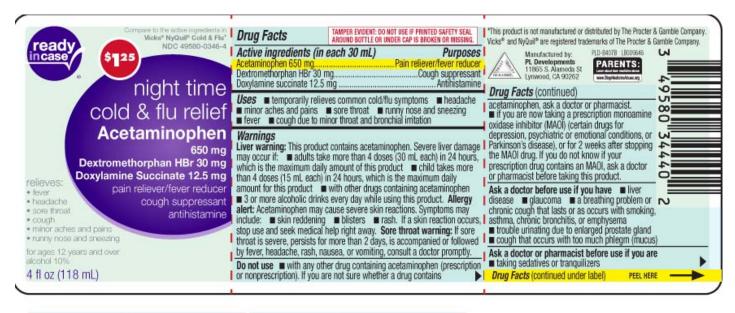
Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

### **Product Label**



#### Drug Facts (continued)

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 fredness 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 (overdose) may 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 children even if you do not notice any signs or symptoms.

#### Drug Facts (continued)

Directions ■ do not take more than directed (see
Overdose warning) ■ do not take more than 4 doses in
any 24-hour period ■ measure only with dosing cup
provided. Do not use any other dosing device.

■ mL = milliliter ■ keep dosing cup with product
■ adults and children 12 years and over: 30 mL every 6
hours ■ children under 12 years of age: do not use
■ when using other Daytime or Nighttime products,
carefully read each label to ensure correct dosing

Other information ■ each 30 mL contains:
potassium 5 mg ■ each 30 mL contains: sodium 19 mg
■ store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients acesulfame potassium, alcohol, citric acid, D&C yellow #10, FD&C green #3, FD&C yellow #6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

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**READYinCASE Night time Cold & Flu Relief** 

#### NIGHTTIME COLD AND FLU READYINCASE

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

| Product Information     |                |                    |                |  |
|-------------------------|----------------|--------------------|----------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49580-0346 |  |
| Route of Administration | ORAL           |                    |                |  |

| Active Ingredient/Active Moiety  |                                  |                     |  |  |
|--|----------------------------------|---------------------|--|--|
| Ingredient Name  | Basis of Strength                | Strength            |  |  |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)                           | ACETAMINOPHEN                    | 650 mg<br>in 30 mL  |  |  |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 30 mg<br>in 30 mL   |  |  |
| <b>DOXYLAMINE SUCCINATE</b> (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)                | DOXYLAMINE SUCCINATE             | 12.5 mg<br>in 30 mL |  |  |

| Inactive Ingredients                                |          |  |
|---|----------|--|
| Ingredient Name                                     | Strength |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                 |          |  |
| WATER (UNII: 059QF0KO0R)                            |          |  |
| ACESULFAME POTASSIUM (UNII: 230V73Q5G9)             |          |  |
| ALCOHOL (UNII: 3K9958V90M)                          |          |  |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)            |          |  |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)         |          |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |  |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                 |          |  |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)      |          |  |
| <b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)     |          |  |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)                 |          |  |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)                |          |  |

| Packaging |                      |  |                         |                       |  |
|-----------|----------------------|--|-------------------------|-----------------------|--|
| #         | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1         | NDC:49580-<br>0346-8 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/30/2014              |                       |  |
| 2         | NDC:49580-<br>0346-2 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/30/2014              |                       |  |
| 3         | NDC:49580-<br>0346-4 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/30/2014              |                       |  |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M012  | 11/30/2014              |                       |  |
|                       |   |                         |                       |  |

## Labeler - P & L Development, LLC (101896231)

Revised: 2/2024 P & L Development, LLC