

NIGHT TIME COUGH- dextromethorphan hydrobromide, doxylamine succinate liquid

P & L Development, 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.

Drug Facts

Active ingredients (in each 30 mL)

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Cough suppressant

Antihistamine

Uses

- temporarily relieves cold symptoms
- cough due to minor throat and bronchial irritation
- runny nose and sneezing

Warnings

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.

Ask a doctor before use if you have

- glaucoma
- a breathing problem or chronic cough that lasts or as occurs with smoking, 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.

When using this product

- avoid alcoholic drinks
- excitability may occur, especially in children
- marked drowsiness may occur
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- cough lasts more than 7 days, come back, or is accompanied by fever, rash, or persistent headache

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.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- do not take more than 4 doses in any 24-hour period
- take only as directed
- measure only with dosing cup provided. Do not use any other dosing device
- mL = milliliter
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years of age: do not use

Other information

- **each 30 mL contains;** sodium 29 mg
- store between 20-25°C (68-77°). Do not refrigerate.

Inactive ingredients

alcohol, citric acid, FD&C blue 1, FD&C red 40, 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[®] Cough*

NightTime Cough

all night cough relief

dextromethorphan HBr

doxylamine succinate

relieves

- cough
- runny nose & sneezing

for ages 12 and over

alcohol 10%

cherry flavor

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.

Distributed by:

PL Developments

200 Hicks Street

Westbury, NY 11590

Product Label

| Drug Facts (continued) | |
|-------------------------------|--|
| Directions | ■ 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. ■ keep dosing cup with product ■ take only as directed ■ mL = milliliter ■ adults and children 12 years and over: 30 mL every 6 hours ■ children under 12 years of age: do not use |
| Other information | ■ each 30 mL contains: sodium 29 mg ■ store between 20-25°C (68-77°F). Do not refrigerate. |
| Inactive ingredients | alcohol, citric acid, FD&C blue #1, FD&C red #40, flavors, 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 |

*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 DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

PARENTS:
Learn about your medicine at
www.StopMedicineAbuse.org



Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590



Compare to the active ingredients in
Vicks® NyQuil® Cough*

NDC 49580-0499-2

nighttime
cough
all night cough relief

dextromethorphan HBr
cough suppressant
doxylamine succinate
antihistamine

relieves:

- cough
- runny nose & sneezing

for ages 12 years & over
alcohol 10%

12 fl oz (355 mL)



cherry flavor

| Drug Facts | |
|--|-------------------|
| Active ingredients (in each 30 mL) | Purposes |
| Dextromethorphan HBr 30 mg..... | Cough suppressant |
| Doxylamine succinate 12.5 mg..... | Antihistamine |
| Uses ■ temporarily relieves cold symptoms ■ cough due to minor throat and bronchial irritation ■ runny nose and sneezing | |
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| Ask a doctor before use if you have ■ glaucoma ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem or chronic cough that lasts or 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. | |
| When using this product ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery | |
| Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. 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. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. | |

READYinCASE NightTime Cough

NIGHT TIME COUGH

dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49580-0499 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|---------------------|
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII: 7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 30 mg in 30 mL |
| DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII: 95QB77JKPL) | DOXYLAMINE SUCCINATE | 12.5 mg in 30 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY) | |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) | |

Product Characteristics

| | | | |
|----------|--------|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49580-0499-4 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/31/2017 | 12/31/2025 |
| 2 | NDC:49580-0499-2 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 12/31/2017 | 12/31/2025 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 12/31/2017 | 12/31/2025 |

Labeler - P & L Development, LLC (101896231)

Revised: 5/2023

P & L Development, LLC