

NIGHT TIME COUGH- dextromethorphan hydrobromide, doxylamine succinate liquid
Safeway, Inc.

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
- 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
- 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, comes back, or is accompanied by fever, rash, or persistent headache.

These could be sign 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-hours 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, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

Call **1-888-723-3929 Monday-Friday 7AM-6PM PST**

Principal Display Panel

Compare to Vicks® NyQuil® Cough active ingredients*

NightTime Cough Relief

DEXTROMETHORPHAN HBr 30 mg - Cough Suppressant

DOXYLAMINE SUCCINATE 12.5 mg - Antihistamine

CHERRY FLAVOR

- Sneezing, runny nose, cough
- For ages 12 years & over
- Nighttime relief
- 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 DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

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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 1-888-723-3929 Monday-Friday 7AM-6PM PST

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Compare to Vicks® NyQuil® Cough active ingredients*

NDC 21130-499-12

Nighttime Cough Relief

DEXTROMETHORPHAN HBr 30 mg
- Cough Suppressant
DOXYLAMINE SUCCINATE 12.5 mg
- Antihistamine

CHERRY FLAVOR

- Sneezing, runny nose, cough
- For ages 12 years & over
- Nighttime relief
- Alcohol 10%

12 FL OZ (355 mL)

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Active ingredients (in each 30 mL) Dextromethorphan HBr 30 mg..... Cough suppressant Doxylamine succinate 12.5 mg.....Antihistamine
Purposes
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 ■ 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.

SIGNATURE CARE Nighttime Cough Relief

NIGHT TIME COUGH

dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:21130-499

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:21130-499-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/31/2018	

Labeler - Safeway, Inc. (009137209)