# COUGH RELIEF NIGHTTIME- dextromethorphan hydrobromide, doxylamine succinate liquid QUALITY CHOICE (Chain Drug Marketing Association)

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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#### **Drug Facts**

# Active ingredients (in each 30 mL)

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

# **Purposes**

Cough suppressant

**Antihistamine** 

#### Uses

- temporarily relieves cold symptoms
  - $\circ\hspace{0.1cm}$  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 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) immediatly.

#### **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, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

# Questions or comments?

Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

\*Compare to the Active Ingredients in VICKS® NYQUIL® Cough

# **Nighttime Cough**

#### **Cough Relief**

Dextromethorphan HBr | Cough Suppressant

Doxylamine Succinate | Antihistamine

For Relief of:

cough | Runny Nose & Sneezing

For Ages 12 & Over

Alcohol 10 %

FL OZ (mL)

**CHERRY FLAVOR** 

\*This product is not manufactured or distributed by The Proctor & Gamble Company.Vicks® 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.

Distributed by C.D.M.A., Inc.©

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Novi, MI 48375

www.qualitychoice.com

#### **Product Label**



# **COUGH RELIEF NIGHTTIME**

dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-292
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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: 3M)Q0SDW1A)		
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		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:63868- 292-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2018	

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

OTC monograph final part341 07/31/2018

# Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 5/2023 QUALITY CHOICE (Chain Drug Marketing Association)