

COUGH RELIEF NIGHTTIME- dextromethorphan hydrobromide, doxylamine succinate liquid
Freds Inc

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

Purposes

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)
- breathing problems 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) 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 **1-877-753-3935 Monday-Friday 9AM-5PM PST**

Principal Display Panel

NIGHTTIME

Cough Relief

Each dose (per 30 mL) of oral solution contains:

30 mg-Dextromethorphan HBr- Cough Suppressant

12.5 mg-Doxylamine Succinate- Antihistamine

- Sneezing, runny nose
- cough

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

Alcohol 10% • Ages 12 +

FL OZ (mL)

CHERRY FLAVOR

*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.

DISTRIBUTED BY: fred's

4300 NEW GETWELL RD., MEMPHIS, TN 38118

www.fredsinc.com

Product Label

Drug Facts (continued)

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fred's
Pharmacy

NDC 55315-499-12

CHERRY FLAVOR

NIGHTTIME

Cough Relief

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30 mg - Dextromethorphan HBr (Cough suppressant)
12.5 mg - Doxylamine Succinate (Antihistamine)

• Sneezing, Runny Nose
• Cough

Alcohol 10% • Ages 12+

12 FL OZ (355 mL)

Compare to the Active Ingredients in
Vicks® NyQuil® Cough*

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FRED'S PHARMACY Nighttime Cough Relief

COUGH RELIEF NIGHTTIME

dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-499
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:55315-499-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/31/2018	04/26/2024

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/31/2018	04/26/2024

Labeler - Freds Inc (005866116)

Revised: 10/2021

Freds Inc