NIGHT TIME COUGH - dextromethorphan hbr, doxylamine succinate liquid
Kareway Product, 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 dose cup)

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold symptoms:

- cough
- 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.
- to make a child sleep

Ask a doctor before use if you have

- glaucoma
- excessive 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
- a sodium-restricted diet

When using this product

- **do not use more than directed**
- 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 right away.

Directions

- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours

adults and children 12 years and over	2 TBSP (30ml) every 6 hours
children under 12 years	ask a doctor

Other information

- **each 30mL dose cup contains**: sodium 36 mg
- store at room temperature

Inactive ingredients

alcohol, citric acid, FD and C blue no.1, FD and C red no.40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate, sucrose, sucralose, xanthan gum

Package label

Night Time Cough Relief

NIGHT TIME COUGH

dextromethorphan hbr, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-0503
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 15 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67510-0503-4	120 mL in 1 BOTTLE		
2	NDC:67510-0503-6	177 mL in 1 BOTTLE		
3	NDC:67510-0503-1	295 mL in 1 BOTTLE		
4	NDC:67510-0503-2	354 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/11/2012	

Labeler - Kareway Product, Inc. (121840057)