

**NIGHT TIME COLD/FLU RELIEF ORIGINAL- acetaminophen, 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 30mL dose cup)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

- temporarily relieves common cold/flu symptoms:
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Warnings

Liver warning

- This product contains acetaminophen. Severe liver damage may occur if you take
- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Sore throat warning:

- If sore throat is severe, persists for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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

- liver disease
- 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
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers.
- taking the blood thinning drug warfarin

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

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.
- 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.

Overdose warning

- Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed - see Overdose warning
- use dose cup or tablespoon (TBSP)
- do not exceed 4 doses per 24 hours

adults and children 12 yrs and over	30 ml (2 Tbsp) every 6 hours
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each 30 mL dose cup contains: sodium 11.32 mg
- store at room temperature

Inactive ingredients

cherry extract, citric acid, ethanol, FD and C blue no.1, FD and C yellow no.5, high fructose corn syrup, I-menthol, methyl p-hydroxybenzoate, polyethylene glycol 400, polysorbate 80, propyl p-hydroxybenzoate, propylene glycol, purified water, sodium citrate, sodium saccharin

Questions or Comments?

1-800-883-0085

Package Label

Nighttime Cold and Flu

<p>TAMPER EVIDENT: Do not use if printed shrink band is missing or broken.</p> <p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if ■ pain or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. Overdose warning: Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Directions ■ take only as directed - see Overdose warning ■ use dose cup or tablespoon (TBS) ■ do not exceed 4 doses per 24 hrs</p> <table border="1"> <tr> <td>adults & children 12 yrs & over</td> <td>30 mL (2 TBS) every 6 hrs</td> </tr> <tr> <td>children 4 to under 12 yrs</td> <td>ask a doctor</td> </tr> <tr> <td>children under 4 yrs</td> <td>do not use</td> </tr> </table> <p>Other information ■ each 30 mL dose cup contains: sodium 11.32 mg ■ store at room temperature</p> <p>Inactive ingredients cherry extract, citric acid, ethanol, FD&C Blue no. 1, FD&C Yellow no. 5, high fructose corn syrup, I-Menthol, methyl p-hydroxybenzoate, polyethylene glycol 400, polysorbate 80, propyl p-hydroxybenzoate, propylene glycol, purified water, sodium citrate, sodium saccharin.</p> <p>Questions or Comments? 1-800-883-0085</p> <p><small>*This product is not manufactured by Procter & Gamble Company, owner of the registered trademark Nyquil®.</small></p> <p>Distributed by: Kareway Product Inc. Compton, CA 90220 Made in Korea W#1005684 ITEM#1562</p> 	adults & children 12 yrs & over	30 mL (2 TBS) every 6 hrs	children 4 to under 12 yrs	ask a doctor	children under 4 yrs	do not use	 <p>COMPARE TO THE ACTIVE INGREDIENTS IN NYQUIL® COLD & FLU RELIEF*</p> <p>NDC 67510-1562-1</p> <p>Nighttime Relief</p> <ul style="list-style-type: none"> • Aches, Fever & Sore Throat • Sneezing, Runny Nose • Cough <p>NIGHTTIME</p> <p>Cold & Flu Relief</p> <p>Acetaminophen Doxylamine Succinate Dextromethorphan HBr</p> <p>10% ALCOHOL ORIGINAL FLAVOR</p> <p>NET 10 FL OZ (295 mL)</p> 	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredients (in each 30 mL dose cup)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Acetaminophen 650 mg</td> <td>Pain reliever/fever reducer</td> </tr> <tr> <td>Dextromethorphan HBr 30 mg</td> <td>Cough suppressant</td> </tr> <tr> <td>Doxylamine succinate 12.5 mg</td> <td>Antihistamine</td> </tr> </tbody> </table> <p>Uses temporarily relieves common cold/flu symptoms: ■ cough due to minor throat and bronchial irritation ■ sore throat ■ headache ■ minor aches and pains ■ fever ■ runny nose and sneezing</p> <p>Warnings Liver warning This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses in 24 hours, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product.</p> <p>Sore throat warning If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, headache, rash, nausea, or vomiting, see a doctor promptly.</p> <p>Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ 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</p> <p>Ask a doctor before use if you have ■ liver disease ■ 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 ■ a sodium-restricted diet</p> <p>Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin</p> <p>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 ▶</p>	Active ingredients (in each 30 mL dose cup)	Purpose	Acetaminophen 650 mg	Pain reliever/fever reducer	Dextromethorphan HBr 30 mg	Cough suppressant	Doxylamine succinate 12.5 mg	Antihistamine
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NIGHT TIME COLD/FLU RELIEF ORIGINAL

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 7510-1562
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-1562-1	295 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/12/2013	

Labeler - Kareway Product, Inc. (121840057)

Revised: 12/2013

Kareway Product, Inc.