

**NIGHT TIME GELCAP- acetaminophen, dextromethorphan, doxylamine capsule, liquid filled
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 GelCap)

Acetaminophen 325mg

Dextromethorphan HBr 15mg

Doxylamine succinate 6.25mg

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 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

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.

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

Ask a doctor or pharmacist before use if you are

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

When using this product

Enter section text here

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

Enter section text here

Overdose warning:

Taking more than directed 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 to adults and children even if you do not notice any signs or symptoms.

Directions

- take only as directed-see Overdose warning
- do not exceed 4 doses per 24 hours

adults and children 12 yrs and over	2 GelCaps with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- store at room temperature

Inactive ingredients

FDC yellow no. 5, dioxide, FDC blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water and sobital special

Pure-Aid Nighttime Gelcap

Pure-Aid™
NightTime
COLD & FLU
Nighttime Relief

Pure-Aid™
NightTime COLD & FLU
Nighttime Relief

NDC No. 67510-0521-0

**Compare to active ingredients in NYQUIL®*

NightTime

COLD & FLU

Nighttime Relief
Original Flavor
Acetaminophen, Doxylamine, Dextromethorphan

- Aches, Fever & Sore Throat
- Sneezing, Runny Nose
- Cough

20 GELCAPS

Pure-Aid™
NightTime COLD & FLU
Nighttime Relief

Pure-Aid™
NightTime COLD & FLU
Nighttime Relief

Drug Facts (continued)

When using this product ■ do not use more than directed ■ especially in children ■ avoid alcoholic drinks ■ marked drowsiness may occur ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, & tranquilizers may increase drowsiness ■ Doxylamine succinate 6.25 mg ■ Acetaminophen 325 mg ■ Dextromethorphan HBr 15 mg ■ Part relever/rever reducer ■ Cough suppressant ■ Arhstamine

Uses ■ temporarily relieves common cold/flu symptoms: ■ cough ■ minor throat & bronchial irritation ■ sore throat ■ headache ■ Doxylamine succinate 6.25 mg ■ Acetaminophen 325 mg ■ Dextromethorphan HBr 15 mg ■ Part relever/rever reducer ■ Cough suppressant ■ Arhstamine

Warnings ■ Liver warning ■ This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4 doses in 24 hrs, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks daily while using this product ■ Sore throat warning ■ 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. ■ Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are unsure 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 ■ Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

Other information ■ store at room temperature ■ children under 4 yrs do not use ■ ask a doctor ■ children 4 to under 12 yrs ■ adults & children 12 yrs & over ■ 2 Gelcaps with water every 6 hrs ■ do not exceed 4 doses per 24 hrs ■ take only as directed - see Overdose warning

Directions ■ you do not notice any signs or symptoms. ■ get medical help or contact Poison Control Center right away. ■ If pregnant or breast-feeding, ask a health professional before use. ■ Keep out of reach of children. Overdose warning: taking more than these could be signs of a serious condition. ■ cough comes back or occurs with rash or headache that lasts. ■ redness or swelling is present ■ new symptoms occur ■ 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 ■ coughing or sneezing is present ■ 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 ■ coughing or sneezing is present ■ new symptoms occur ■ redness or swelling is present ■ cough comes back or occurs with rash or headache that lasts. ■ If pregnant or breast-feeding, ask a health professional before use. ■ Keep out of reach of children. Overdose warning: taking more than these could be signs of a serious condition. ■ do not use more than directed ■ especially in children ■ avoid alcoholic drinks ■ marked drowsiness may occur ■ be careful when driving a motor vehicle or operating machinery ■ alcohol, sedatives, & tranquilizers may increase drowsiness ■ Doxylamine succinate 6.25 mg ■ Acetaminophen 325 mg ■ Dextromethorphan HBr 15 mg ■ Part relever/rever reducer ■ Cough suppressant ■ Arhstamine

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Active ingredients (in each Gelcap)

CAUTION ■ Failure to follow these warnings could result in serious consequences. Use only if blister are intact. If difficult to open, use scissors. TAMPER EVIDENT. This package is safety sealed and child resistant.

NIGHT TIME GELCAP

acetaminophen, dextromethorphan, doxylamine capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0521
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL, (R)- (UNII: 602HN5L69H)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	24mm
Flavor		Imprint Code	NYTIME
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0521-1	1 in 1 BOX		
1		10 in 1 BLISTER PACK		
2	NDC:67510-0521-2	1 in 1 BOX		
2		12 in 1 BLISTER PACK		

3	NDC:67510-0521-0	2 in 1 BOX		
3		20 in 1 BLISTER PACK		
4	NDC:67510-0521-4	2 in 1 BOX		
4		24 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/01/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 5/2011

Kareway Product, Inc.