DAY TIME GELCAP - acetaminophen, dextromethorphan, phenylephrine 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 10mg

Phenylephrine HCl 5mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal decongestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

Warnings

Enter section text here

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.

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phegm(mucus)
- Persistent or chronic cough as occurs with smoking, asthma, emphysema

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product, do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms get worse or last more than 5 days (children) or 7 days (adults)
- 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 red no. 40, FDC yellow no. 5, dioxide, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water and sobital special

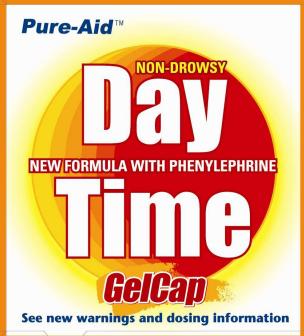
Daytime gelcap





COLD/FLU Relief





in DayQUIL®

Relieves

- Coughing

Without Drowsiness!

Acetaminophen

Dextromethorphan Hbr Phenylephrine

COLD/FLU Relief









Exclusively distributed by:

Made in Kores

Made in Kores

"This product is not manufactured by Procter & Gamble, owner of the registered trademark Dayquil@. Inactive ingredients FD&C red no.40, FD&C yellow no.5, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, and sorbitol special

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Drug Facts (continued)

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Active ingredients (in each GelCap) Purpose

Drug Facts

-ailure to follow these warnings could result in serious consequences.





DAY TIME GELCAP

acetaminophen, dextromethorphan, phenylephrine capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0523
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDONE (UNII: FZ989GH94E)		
PROPYLENE GLYCOL, (R)- (UNII: 602HN5L69H)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	orange	Score	no score
Shape	CAPSULE	Size	24mm
Flavor		Imprint Code	DYTIME
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:67510-0523-1	1 in 1 BOX			
1	10 in 1 BLISTER PACK			
2 NDC:67510-0523-2	1 in 1 BOX			
2	12 in 1 BLISTER PACK			
3 NDC:67510-0523-0	2 in 1 BOX			
3	20 in 1 BLISTER PACK			
4 NDC:67510-0523-4	2 in 1 BOX			
4	24 in 1 BLISTER PACK			

Marketing Information				
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
- 1				

OTC monograph final part341 06/01/2011

Labeler - Kareway Product, Inc. (121840057)

Revised: 5/2011 Kareway Product, Inc.