

**DAY TIME COLD/FLU RELIEF - acetaminophen, dextromethorphan, phenylephrine 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 15 ml tablespoon)

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

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Liver warning

This product contains acetaminophen. Severe liver damage may occur if adult/child takes

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day 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 phlegm(mucus)
- Persistent or chronic cough as occurs with smoking, asthma, emphysema
- a sodium-restricted diet

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 for adults and 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 6 to under 12 yrs	15 ml (1 TBSP) every 4 hours
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- each tablespoon contains: sodium 50mg
- store at room temperature

Inactive ingredients

citric acid, FDC red no.40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate, sucralose, sucrose, xanthan gum

Daytime Cold/Flu Relief

TAMPER EVIDENT: Do not use if printed shrinkband is missing or broken.

Drug Facts (continued)

■ 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.

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 hrs

adults & children 12 yrs & over	30 mL (2 TBSP) every 4 hrs
children 6 to under 12 yrs	15 mL (1 TBSP) every 4 hrs
children 4 to under 6 yrs	ask a doctor
children under 4 yrs	do not use

Other information ■ each 30 mL dose cup contains: sodium 50 mg
■ store at room temperature

Inactive ingredients citric acid, FD&C red no.40, flavor, glycerin, polyethylene glycol 400, propylene glycol, polysorbate 80, purified water, sodium citrate, sodium saccharin, sucralose, sucrose, xanthan gum

*This product is not manufactured by Procter & Gamble, owner of the registered trademark Dayquil®.

KAREWAY
Exclusively distributed by:
Kareway Product Inc. Compton, CA 90220
Made in Korea



NDC No. 67510-0544-4

Pure-Aid™

*Compare to active ingredients in DAYQUIL®

Day Time

COLD & FLU

Multi-Symptom Relief
Acetaminophen, Phenylephrine, Dextromethorphan

- Aches, Fever & Sore Throat
- Nasal Congestion
- Cough

Non-Drowsy
Alcohol Free / Antihistamine Free

NET 4 FL OZ (120 mL)

Drug Facts

Active ingredients (in each 15 mL tablespoon) **Purpose**

Acetaminophen 325 mg Pain reliever/fever reducer

Dextromethorphan HBr 10 mg Cough suppressant

Phenylephrine HCl 5 mg Nasal decongestant

Uses temporarily relieves common cold/flu symptoms:
■ nasal congestion ■ cough due to minor throat & bronchial irritation
■ sore throat ■ headache ■ minor aches & pains ■ fever

Warnings **Liver warning** This product contains acetaminophen. Severe liver damage may occur if adult/child takes ■ more than 4 doses in 24 hours, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen ■ adult has 3 or more alcoholic drinks every day 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 phlegm (mucus) ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema ■ a sodium-restricted diet

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)

DAY TIME COLD/FLU RELIEF

acetaminophen, dextromethorphan, phenylephrine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0544
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0544-4	120 mL in 1 BOTTLE		
2	NDC:67510-0544-6	177 mL in 1 BOTTLE		
3	NDC:67510-0544-0	295 mL in 1 BOTTLE		
4	NDC:67510-0544-2	354 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/06/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 7/2012

Kareway Product, Inc.