

DAY TIME- acetaminophen, dextromethorphan hydrobromide and phenylephrine hydrochloride solution

Kroger Company

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.

Kroger Co. DayTime Drug Facts

Active ingredients (in each 15 mL tablespoon)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 4 doses (adult: 2,600 mg acetaminophen; child: 1,300 mg acetaminophen) in 24 hours. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken 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, consult 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or 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
- pain, nasal congestion or cough gets worse or lasts 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.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) 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 Liver warning
 - use dose cup
 - 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

- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information

- each tablespoon contains: sodium 7 mg
- store at 20°-25°C (68°-77°F)

Inactive ingredients

butylated hydroxyanisole, edetate disodium, FD&C yellow no. 6, flavor, glycerin, menthol, monobasic sodium phosphate, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sucrose, xanthan gum

Questions or comments?

1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredients of VICKS® DAYQUIL® COLD & FLU

See back panel

NON-DROWSY

DAY TIME

COLD & FLU

Acetaminophen, Pain Reliever/Fever Reducer

Dextromethorphan HBr, Cough Suppressant

Phenylephrine HCl , Nasal Decongestant

Relieves:

Aches, Fever, Sore Throat

Nasal Congestion

Coughs

Alcohol Free

Antihistamine Free

12 FL OZ (354 mL)

Drug Facts (continued)

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
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 CINCINNATI, OHIO 45202

QUALITY GUARANTEE
 www.kroger.com

GLUTEN FREE



COMPARE TO the active ingredients of
 VICKS® DAYQUIL® COLD & FLU *See side panel

NDC 30142-656-40



FROM OUR FAMILY
 TO YOURS



DayTime

COLD & FLU

Acetaminophen, Pain Reliever/Fever Reducer
 Dextromethorphan HBr, Cough Suppressant
 Phenylephrine HCl, Nasal Decongestant

Relieves:

- Aches, Fever, Sore Throat
- Nasal Congestion
- Coughs

Alcohol Free
 Antihistamine Free



12 FL OZ (354mL)

Drug Facts Do not use if printed neckband is broken or missing

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: ■ headache
 ■ sore throat ■ minor aches and pains ■ nasal congestion
 ■ fever ■ cough due to minor throat and bronchial irritation

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Ask a doctor before use if you have ■ liver disease ■ diabetes ■ thyroid disease ■ high blood pressure ■ heart disease ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

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: 65640 45 F6

DAY TIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:30 142-656
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE	
EDETATE DISODIUM	
FD&C YELLOW NO. 6	
GLYCERIN	
SODIUM PHOSPHATE, MONOBASIC	
POLYETHYLENE GLYCOLS	
PROPYLENE GLYCOL	
WATER	
SACCHARIN SODIUM	
SUCROSE	

XANTHAN GUM	
MENTHOL	

Product Characteristics

Color	ORANGE (clear)	Score	
Shape		Size	
Flavor	MENTHOL (with fruit)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-656-38	295 mL in 1 BOTTLE		
2	NDC:30 142-656-40	354 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/11/2006	

Labeler - Kroger Company (006999528)

Revised: 11/2014

Kroger Company