

DAYTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

The Kroger Co.

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)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - fever
 - nasal congestion
 - cough due to minor throat and bronchial irritation

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if:

- adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
- child takes more than 4 doses (15 mL each) in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

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

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- a sodium-restricted diet
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if the user is

taking the blood thinning drug warfarin.

When using this product,

do not exceed recommended dosage.

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- 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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

- **do not take more than directed (see overdose warning)**
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL=milliliter

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

- **When using Day Time and Night Time products, carefully read each label to ensure correct dosing**

Other information

- **each 15 mL contains:** sodium 12 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-800-632-6900**

Principal Display Panel

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

POWERFUL NON-DROWSY RELIEF

Cold & Flu

DAYTIME

Multi-Symptom Relief

Acetaminophen

Dextromethorphan HBr

Phenylephrine HCl

Pain Reliever

Fever Reducer

Cough Suppressant

Nasal Decongestant

For Ages 6 Years & Older

Antihistamine Free

Alcohol Free

FL OZ (mL)

*Vicks® and DayQuil® are registered trademarks of The Procter & Gamble Company, Cincinnati, OH 45202. The Procter & Gamble Company is not affiliated with The Kroger Co. or this Product.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202
www.kroger.com

Package Label

Drug Facts (continued)

Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occur
■ pain, nasal congestion, or cough gets worse, or lasts more than 5 days (children) or 7 days (adult) ■ 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 (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 ■ do not take more than directed (see Overdose warning) ■ do not take more than 4 doses in any 24-hour period ■ measure only with dosing cup provided. Do not use any other dosing device. ■ mL = milliliter ■ keep dosing cup with product

adults and children 12 years and over	30 mL every 4 hours
children 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

■ when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

Other information ■ each 15 mL contains: sodium 12 mg ■ store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments? Call 1-800-632-6900

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CINCINNATI, OHIO 45202
QUALITY GUARANTEE
800-632-6900 | www.kroger.com
GLUTEN FREE

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org
PLD-A380D LB008049

COMPARE TO the active ingredients of VICKS® DAYQUIL® COLD & FLU *See back panel NDC 30142-666-12

Cold & Flu

DayTime

Multi-Symptom Relief

Acetaminophen
Dextromethorphan HBr
Phenylephrine HCl

POWERFUL NON-DROWSY RELIEF

Pain Reliever
Fever Reducer
Cough Suppressant
Nasal Decongestant

For Ages 6 Years & Older
Antihistamine Free
Alcohol Free

12 FL OZ (355 mL)

Drug Facts TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

Active ingredients (in each 15 mL)

Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Purposes

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

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if: ■ adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
■ child takes more than 4 doses (15 mL each) in 24 hours ■ taken with other drugs containing acetaminophen ■ adult has 3 or more alcoholic drinks every day while using this product. **Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash. If a skin reaction occurs, stop use and seek medical help right away. **Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or 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.

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

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

When using this product, do not exceed recommended dosage.

KROGER DayTime Cold & Flu Relief

DAYTIME COLD AND FLU			
acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-6 66
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-666-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/30/2020	

Labeler - The Kroger Co. (006999528)

Revised: 11/2020

The Kroger Co.