COLD AND FLU RELIEF- acetaminophen dextromethorphan hbr phenylephrine hcl liquid

QUALITY CHOICE (Chain Drug Marketing Association)

Drug Facts

Active ingredients (in each 15 mL)

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

Warnings

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

- adult take 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 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.

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 as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if 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 occur
- 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) can cause serious 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 and 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 children12 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

Principal Display Panel

*Compare to the active ingredients in Vicks® DayQuil® Cold & Flu

Non-Drowsy

Multi-Symptom

Daytime

Cold & Flu Relief

Acetaminophen 325 mg

Pain reliever/Fever reducer

Dextromethorphan HBr 10 mg

Cough suppressant

Phenylephrine HCl 5 mg

Nasal decongestant

Relieves

- Aches, fever & sore throat
- Cough
- Nasal congestion

For ages 6 years and over

Alcohol-free

Antihistamine-free

FL OZ (mL)

*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks® and DayQuil® are registered trademarks of The Procter & Gamble Company.

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

DISTRIBUTED BY:

Product Label

NDC XXXXX-XXX-XX

*Compare to the active ingredients in Vicks® DayQuil® Cold & Flu

Non-Drowsy Multi-Symptom

Daytime Cold & Flu Relief

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

Relieves

- √ Aches, fever & sore throat
- √ Cough
- ✓ Nasal congestion

For ages 6 years and over Alcohol-free Antihistamine-free

8 fl oz (237 mL)

Drug Facts

Active ingredients (in each 15 mL)

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

Uses

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PLD-A380D LB009713

LB009715

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

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PEEL CORNER FOR MORE DRUG FACTS

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Ask a doctor before use if you have

- liver disease heart disease
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- 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.

Drug Facts (continued)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
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Drug Facts (continued)

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under 12 years	4 hours
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Other information

- each 15 mL contains: sodium 12 mg
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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

QUALITY CHOICE Daytime Cold & Flu Relief

COLD AND FLU RELIEF

acetaminophen dextromethorphan hbr phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-168
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITOL (UNII: 506T60A25R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
XANTHAN GUM (UNII: TTV12P4NEE)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:83324- 168-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/31/2024	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 4/2024

QUALITY CHOICE (Chain Drug Marketing Association)