DAYTIME COLD AND FLU MULTI SYMPTOM RELIEF- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid Family Dollar (FAMILY WELLNESS)

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

Dextromethoprhan HBr 10 mg
Phenlyephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves common cold and 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) 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

Allery 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 the user has

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

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.

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 a	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 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® DAYQUIL® COLD & FLU

Daytime

Cold & Flu Relief

Acetaminophen Dextromethorphan HBr Phenylephrine HCL

MULTI-SYMPTOM

- aches, fever, sore throat
- nasal congestion
- cough

Alcohol-free

Antihistamine-free

FL OZ (mL)

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

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DISTRIBUTED BY:

MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY, CHESAPEAKE, VA 23320

Package Label



FAMILY WELLNESS Daytime Cold & Flu Relief

DAYTIME COLD AND FLU MULTI SYMPTOM RELIEF acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-066

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	
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)		

Ш	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:55319- 066-10	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2015	08/31/2025		
	NDC:55319- 066-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/31/2015	08/31/2025		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part341	08/31/2015	08/31/2025		

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 1/2023