FAMILY DOLLAR DAYTIME COLD AND FLU RELIEF- acetaminohpen, dextromethorphan hbr, phenylephrine hcl liquid FAMILY DOLLAR SERVICES 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.

Family Dollar DayTime Cold and Flu Relief

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 common cold/flu symptoms:

Warnings

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

- adult takes more than 4 doses (30 mL) in 24 hours which is maximum daily amount for this product
- child takes more than 4 doses (15 mL) in 24 hours, which is the maximum daily amount for this product
- 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 non-prescription). 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
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such 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
- 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 a 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 (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

- take only as directed
- only use the dose cup provided
- do not exceed 4 doses per 24 hours

Adults & children 12 yrs & over	30 mL every 4 hrs.
Children 6 to under 12 yrs	15 mL every 4 hrs
Children 4 to under 6 yrs	Ask a doctor
Children under 4 yrs.	Do not use

Other information

- each 15 mL contains: sodium 42 mg
- store at room temperature. Do not refrigerate

Inactive ingredients

Anhydrous citric acid, disodium edetate, FD&C Yellow No 6, flavor, glycerin, menthol, potassium citrate, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium chloride, sorbitol, sucralose, xanthan gum

Questions or comments?

1-866-467-2748

Principal Display Panel

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

NDC 55319-912-12

Day Time

Cold & Flu Relief

Acetaminophen, Phenylephrine HCI,

Dextromethorphan HBr

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal congestion & Sinus Pressure
- Cough

12 FL OZ (354 mL)

DO NOT USE IF IMPRINTED SHRINK BAND IS MISSING OR BROKEN Distributed by:

*This product.is not manufactured or distributed by Procter & Gamble, the distributor of Vicks® Dayquil™ Cold & Flu.

FRONT









FAMILY DOLLAR DAYTIME COLD AND FLU RELIEF

acetaminohpen, dextromethorphan hbr, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-912
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	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		

GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POTASSIUM CITRATE ANHYDROUS (UNII: 86R1NVR0HW)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:55319- 912-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/07/2023	

Labeler - FAMILY DOLLAR SERVICES INC (024472631)

Revised: 7/2023 FAMILY DOLLAR SERVICES INC