## FAMILY DOLLAR NIGHTTIME COLD AND FLU RELIEF ORIGINAL FLAVORacetaminophen, dextromethorphan hbr, doxylamine succinate solution FAMILY DOLLAR SERVICES INC

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# Family Dollar Nighttime Cold & Flu Relief Drug Facts

## Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

#### **Purpose**

Pain reliever/fever reducer

Cough suppressant

Antihistamine

#### Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

# Warnings

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

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, or chronic bronchitis or emphysema
- trouble urinating due to an enlarged prostate gland

# Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

# When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

# Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- 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:** 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
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

#### Other information

- each 30 mL contains: sodium 16 mg
- store at room temperature and do not refrigerate

#### **Inactive ingredients**

anhydrous citric acid, D&C Yellow No. 10, disodium edetate, FD&C Green No. 3, FD & C Yellow No 6, flavors, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol liquid, sucralose.

#### Questions or comments?

1-866-467-2748

# Package/Label Principal Display Panel

Compare to the active ingredients in VICKS<sup>®</sup> Nyquil<sup>™</sup>Cold & Flu\*

NDC 55319-692-12

# Nighttime Cold & Flue Relief

Acetaminophen, Dextromethorphan succinate,

Doxylamine HBr

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sneezing, Runny Nose
- Cough

# **Original Flavor**

12 FL OZ (354 mL)

# TAMPER EVIDENT: 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<sup>®</sup> Nyquil™Cold & Flu\*

#### **FRONT**







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# FAMILY DOLLAR NIGHTTIME COLD AND FLU RELIEF ORIGINAL FLAVOR

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-692 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		

FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:55319-692- 12	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/10/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	07/10/2023		

# Labeler - FAMILY DOLLAR SERVICES INC (024472631)

Revised: 12/2024 FAMILY DOLLAR SERVICES INC