# NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid WALMART INC. (see also Equate)

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.

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#### **Drug Facts**

# Active ingredients (in each 30 mL) Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

### **Purposes**

### Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

#### Uses

- temporarily relieves these common cold/flu symptoms
  - minor aches and pains
  - headache
  - sore throat
  - fever
  - runny nose and sneezing
  - cough due to minor throat and bronchial irritation

# Warnings

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

- more than 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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 is 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
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

## Ask a doctor or pharmacist before use if you are taking

- sedatives or tranquilizers
- 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 last more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts.

These could be a signs of a serious conditions.

# 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 6 hours
- children under 12 years of age: do not use
- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

#### Other information

- each 30 mL contains: potassium 5 mg
- each 30 mL contains: sodium 24 mg
- store between 20-25°C (68-77°F). Do not refrigerate

## Inactive ingredients

acesulfame potassium, alcohol, citric acid. FD&C blue1, FD&C red 40, Flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments? 1-888-287-1915

# **Principal Display Panel**

Compare to Vicks® NyQuil® Cold & Flu active ingredients\*

#### **NIGHTTIME**

#### Cold & Flu

Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

Multi-Symptom Relief

- Acetaminophen Headache, fever, sore throat, minor aches & pains
- Dextromethorphan HBr Cough
- Doxylamine Succinate Sneezing, runny nose

Cherry flavor

10% ALCOHOL

FL OZ (mL)

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

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

DISTRIBUTED BY: WALMART INC.,

Bentonville, AR 72716

#### **Product Label**



**EQUATE Nighttime Cold and Flu Cherry Flavor** 

# NIGHTTIME COLD AND FLU acetaminophen, dextromethorphan hbr, doxylamine succinate liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:79903-173 Route of Administration ORAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	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
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79903- 173-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2022		
2	NDC:79903- 173-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2022		
3	NDC:79903- 173-24	2 in 1 PACKAGE	12/30/2022		
3		355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	12/30/2022		
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