

**NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr,
doxylamine succinate liquid
CVS PHARMACY, INC**

Drug Facts

Active ingredients (in each 30mL)

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 4,000 of acetaminophen in 24 hours
- 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

- 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 an 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 lasts 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 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 24-hours 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 Day Time or Night Time products, carefully read each label to ensure correct dosing**

Other information

- **each 30 mL contains:** potassium 5 mg
- **each 30 mL contains:** sodium 19 mL
- store between 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

acesulfame potassium, alcohol, citric acid, D&C yellow #10, FD&C green #3, FD&C yellow #6,, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

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

Principal Display Panel

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

Multi-Symptom

Nighttime

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

DOXYLAMINE SUCCINATE

Antihistamine

Relieves:

Headache, Fever, Sore throat, Minor aches & pains, Sneezing, Runny nose, Cough

COLD & FLU

Original Flavor

Alcohol 10%

Ages 12+

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:CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

Product Label



Compare to the active ingredients in Vicks® NyQuil® Cold & Flu⁴

NDC 51316-344-12

Multi-Symptom Nighttime

ACETAMINOPHEN

Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr

Cough suppressant

DOXYLAMINE SUCCINATE

Antihistamine

Relieves:
Headache, Fever, Sore throat,
Minor aches & pains, Sneezing,
Runny nose, Cough

COLD & FLU



Original Flavor
Alcohol 10%

Ages 12+

12 FL OZ (355 mL)

PLD-A407B LB009890

Drug Facts

Active ingredients (in each 30 mL) Purposes

Acetaminophen 650 mgPain reliever/fever reducer
Dextromethorphan HBr 30 mgCough suppressant
Doxylamine succinate 12.5 mgAntihistamine

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Discard Bottle, Dosing Cup & Plastic Cap



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www.StopMedicineAbuse.org

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PLD-A407B LB009923

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

Uses

- temporarily relieves common cold/flu symptoms
- minor aches and pains
- headache sore throat
- runny nose and sneezing fever
- 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 4,000 mg of acetaminophen in 24 hours
- 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

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

acetaminophen, ask a doctor or pharmacist.

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Drug Facts (continued)

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Drug Facts (continued)

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CVS HEALTH Multi-Symptom Nighttime Cold & Flu

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-344
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-344-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/15/2023	

Labeler - CVS PHARMACY, INC (062312574)

