

**NIGHTTIME COLD AND FLU RELIEF- acetaminophen dextromethorphan hbr
doxylamine succinate liquid
QUALITY CHOICE (Chain Drug Marketing Association)**

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
- 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 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?

Call

Principal Display Panel

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

NIGHTTIME

Cold & Flu Relief

Acetaminophen 650 mg

Pain reliever/Fever reducer

Dextromethorphan HBr 30 mg

Cough suppressant

Doxylamine succinate

Antihistamine

Relieves

- Headache, fever, sore throat, minor aches & pains
- Sneezing
- Runny nose
- Cough

For ages 12 years and over

Nighttime relief

Alcohol 10%

CHERRY FLAVOR

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:

Product Label

NDC XXXXX-XXX-XX

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

Nighttime Cold & Flu Relief

Acetaminophen 650 mg
Pain reliever/Fever reducer
Dextromethorphan HBr 30 mg
Cough suppressant
Doxylamine succinate 12.5 mg
Antihistamine

Relieves

- ✓ Headache, fever, sore throat, minor aches & pains
- ✓ Sneezing
- ✓ Runny nose
- ✓ Cough

For ages 12 years and over
Nighttime relief

Alcohol 10%



PLD-A4278 LB009732

12 fl oz (355 mL)

Drug Facts

Active ingredients (in each 30 mL)

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

Purposes

Uses

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

*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.



PLD-A4278 LB009732

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

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 acetaminophen, ask a doctor or pharmacist.

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

■ 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, 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
- 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.

Drug Facts (continued)

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.

Drug Facts (continued)

Inactive ingredients acesulfame potassium, alcohol, citric acid, FD&C blue #1, FD&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

QUALITY CHOICE Nighttime Cold & Flu Relief Cherry Flavor

NIGHTTIME COLD AND FLU RELIEF

acetaminophen dextromethorphan hbr doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-158
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: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83324-158-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/31/2024	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 4/2024

QUALITY CHOICE (Chain Drug Marketing Association)