

COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Best Choice (Valu Merchandisers Company)

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.

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 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 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 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 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 24 mg
- store between 20-25°C (68-77°F). Do not refrigerate

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

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*
NIGHTTIME

COLD & FLU RELIEF

MULTI-SYMPTOM 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
- SNEEZING • MINOR ACHES & PAINS
- RUNNY NOSE •COUGH

CHERRY FLAVOR

FL OZ (mL)

FOR AGES 12 YEARS AND OVER

ALCOHOL 10%

NIGHTTIME RELIEF

*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

PROUDLY DISTRIBUTED BY:

VALU MERCHANDISERS, CO.

5000 KANSAS AVE

KANSAS CITY, KS 66106

Product Label

Drug Facts	
Active ingredients (in each 30 mL)	Purposes
Acetaminophen 650 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 30 mg.....	Cough suppressant
Doxylamine succinate 12.5 mg.....	Antihistamine
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	
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.	
■ 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	
← PEEL HERE Drug Facts (continued under label)	



COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL® COLD & FLU*

NIGHTTIME COLD & FLU RELIEF



MULTI-SYMPOM 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
 • SNEEZING • MINOR ACES & PAINS
 • RUNNY NOSE • COUGH

CHERRY FLAVOR

8 FL OZ (237 mL)

FOR AGES 12 YEARS AND OVER
ALCOHOL 10% NIGHTTIME RELIEF

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PARENTS:
 Learn about teen medicine abuse
www.StopMedicineAbuse.org

Best Choice, 100% Guaranteed

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 VALU MERCHANDISERS, CO.
 5000 KANSAS AVE
 KANSAS CITY, KS 66106

PLD-B427B LB005261

BEST CHOICE



Drug Facts (continued)
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
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Drug Facts (continued)
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■ keep dosing cup with product
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■ 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
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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
Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

BEST CHOICE Nigtttime Cold & Flu Relief

COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-343
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)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63941-343-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2016	
2	NDC:63941-343-12	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part341	10/31/2016		

Labeler - Best Choice (Valu Merchandisers Company) (868703513)