

**NIGHT TIME COLD AND FLU READYIN CASE- acetaminophen,
dextromethorphan hydrobromide, doxylamine succinate liquid
P & L Development, LLC**

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
 - fever
 - sore throat
 - 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 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 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
- a sodium-restricted diet

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 6 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 insure correct dosing**

Other information

- **each 30 mL contains:** potassium 10 mg
- **each 30 mL contains:** sodium 38 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***

Night Time

Cold & Flu

Acetaminophen

dextromethorphan HBr

doxylamine succinate

Relieves:

- aches, fever & sore throat
- cough
- runny nose & sneezing

for ages 12 & over

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.

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Product Label

← PEEL HERE **Drug Facts** (continued under 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. ▶

ready in case

Compare to active ingredients in
Vicks® NyQuil® Cold & Flu*
 NDC 49580-0343-6

night time cold & flu
Acetaminophen
 dextromethorphan HBr
 doxylamine succinate

relieves:
 • aches, fever & sore throat
 • cough
 • runny nose & sneezing

for ages 12 & over
 alcohol 10%

6 fl oz (177 mL) cherry flavor



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Manufactured by:
PL Developments
 11865 S. Alameda St
 Lynwood, CA 90262

PARENTS:
 Learn about your medicine online
www.StopMedicineAbuse.org

PLD-B287B LB003857



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Drug Facts (continued)

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

Drug Facts (continued)

smoking, asthma, chronic bronchitis, or emphysema ■ trouble urinating due to enlarged prostate gland ■ a sodium-restricted diet

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 ■ 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. ▶

Drug Facts (continued)

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.

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Drug Facts (continued)

Other information
 ■ each 30 mL contains: potassium 10 mg
 ■ each 30 mL contains: sodium 38 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.

READYinCASE NightTime Cold & Flu Cherry Flavor

NIGHT TIME COLD AND FLU READYIN CASE			
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0343
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
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: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0343-2	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2014	12/31/2026
2	NDC:49580-0343-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2014	12/31/2026
3	NDC:49580-0343-4	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2014	12/31/2026
4	NDC:49580-0343-6	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2014	12/31/2026

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/31/2014	12/31/2026

Labeler - P & L Development, LLC (101896231)

