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

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 15 mL)

Acetaminophen 500 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 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
- itchy nose or throat
- coughs
- 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 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday while using this product

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

- to make a child sleepy
- 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
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have
- liver disease
- glaucoma
- breathing problems
- chronic bronchitis
- a sodium-restricted diet
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma or emphysema or if cough is accompanied by excessive phlegm (mucus)

Ask a doctor or pharmacist before use if you are taking
- sedatives or tranquilizers
- the blood thinning drug warfarin

When using this product
- **do not use more than directed (see overdose warning)**
- 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
- redness or swelling is present
- new symptoms occur
- fever gets worse or last more than 3 days
- pain or cough gets worse or last more than 7 days
- 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) immediately. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
- **take only as recommended (see overdose warning)**
- do not exceed 4 doses per 24 hours
- use dosing cup provided
- mL= milliliter

age	dose
adults & children 12 yrs and over	30 mL every 6 hours

children 4 to 11 yrs	do not use unless directed by a doctor
children under 4 yrs	do not use

- **When using Day Time or Night Time products, carefully read each label to ensure correct dosing.**

Other information

- each 15 mL contains; **sodium 18 mg**
- store at room temperature

Inactive ingredients

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

Principal Display Panel

Compare to active ingredients in Vicks® NyQuil®*

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.

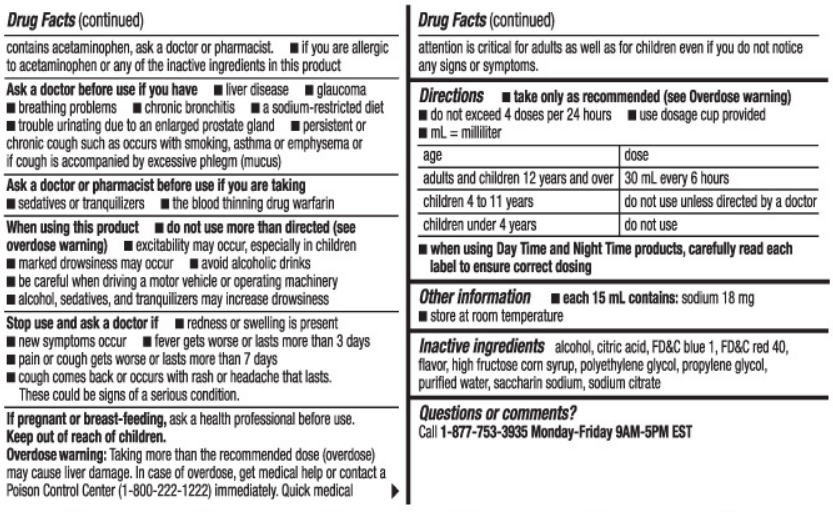
Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Product Label



ReadyinCase NightTime Cold & Flu Cherry Liquid

NIGHT TIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49580-0342
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH)	DEXTROMETHORPHAN	15 mg

(DEXTROMETHORPHAN - UNII:7355X3ROTS)	HYDROBROMIDE	in 15 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 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)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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:49580-0342-1	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2015	
2	NDC:49580-0342-2	355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/28/2015	

Labeler - P & L Development, LLC (101896231)

Revised: 12/2019 P & L Development, LLC