SEVERE COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci liquid
P & L Development, LLC

Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine succinate 12.5 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal Decongestant

Uses

- temporarily relieves common cold/flu symptoms:
  - nasal congestion
  - sore throat
  - headache
  - sinus congestion and pressure
  - minor aches and pain
  - runny nose and sneezing
  - cough due to minor throat and bronchial irritation
- temporarily reduces
  - fever
  - cough to help you sleep
  - swelling of nasal passage
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

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 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 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarges prostate gland
- 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
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking
- taking sedatives or tranquilizers
- taking 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

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or last more than 3 days
- redness or swelling is present
- 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 even if you do not notice any signs or symptoms.

Directions

- **take only as directed - see Overdose warning**
- do not exceed 4 doses per 24 hours
- 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 4 hours
- children under 12 years of age: do not use
- **When using Day Time or Night Time products, carefully read each label to ensure correct dosing.**

Other information

- **each 30 mL contains**; sodium 64 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate

Inactive ingredients

anhydrous citric acid. FD&C blue1, FD&C red 40, Flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

Questions or comments?

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

Principal Display Panel

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

maximum strength

severe

night time

cold & flu relief

Acetaminophen 650 mg

Pain Reliever/Fever Reducer

dextromethorphan HBr 20 mg

Cough Suppressant

doxylamine succinate 12.5 mg

Antihistamine

phenylephrine HCl 10 mg

nasal decongestant

relieves

- ache, Fever, Sore Throat
- cough
- runny nose & sneezing
- nasal & sinus congestion

alcohol free

berry 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 CUPOR UNDER CAP IS BROKEN OR MISSING.

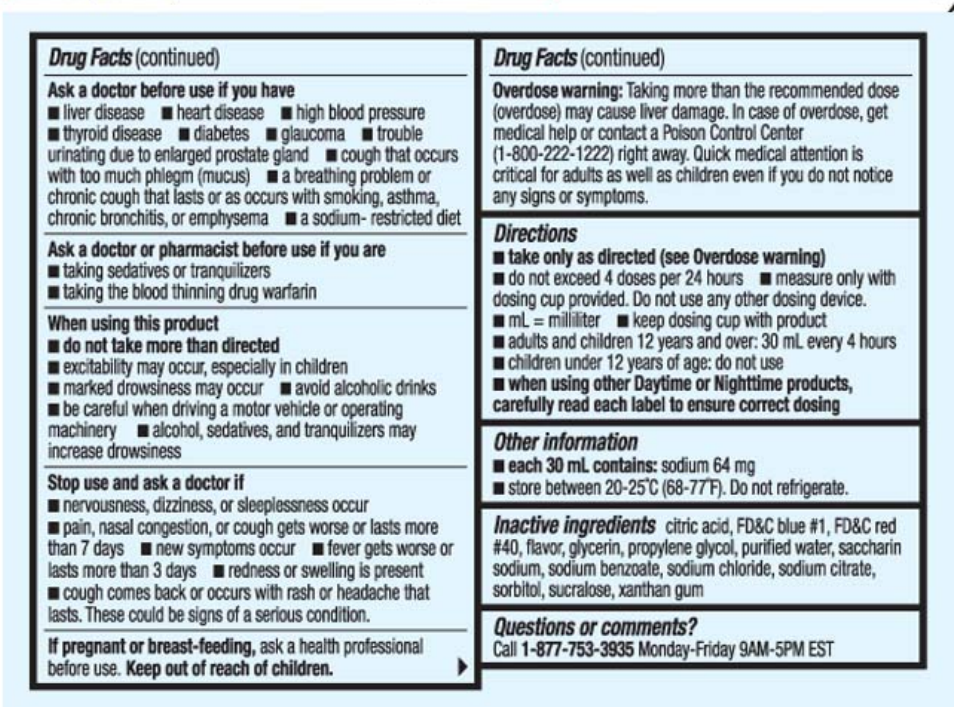
Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Product Label



READYinCASE Nighttime Cold & Flu Relief

SEVERE COLD AND FLU NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49580-4160
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	20 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-4160-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/26/2021	

Labeler - P & L Development, LLC (101896231)