COLD MAX NIGHTTIME- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci 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 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms
  - minor aches and pains
  - headache
  - nasal congestion
  - sore throat
  - runny nose and sneezing
  - cough
  - sinus congestion and pressure
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

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.
- 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
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to enlarged 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

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 exceed recommended dose (see overdose warning)**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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 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 4 hours
- children under 12 years of age: do not use

Other information
- **each 15 mL contains:** sodium 3 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Inactive ingredients

citric acid, ethyl alcohol, FD&C blue #1, flavors, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose

Principal Display Panel

*Compare to the active ingredients in Tylenol® Cold Max Nighttime Cool Burst

nighttime

cold max

Acetaminophen

dextromethorphan HBr

doxylamine Succinate

phenylephrine HCl

For ages 12 years and over

alcohol 0.5%

cool blast flavor

relieves:

- head & body aches
- fever & sore throat
- cough
- nasal congestion
- runny nose & sneezing

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol®Cold Max Nighttime Cool Burst®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

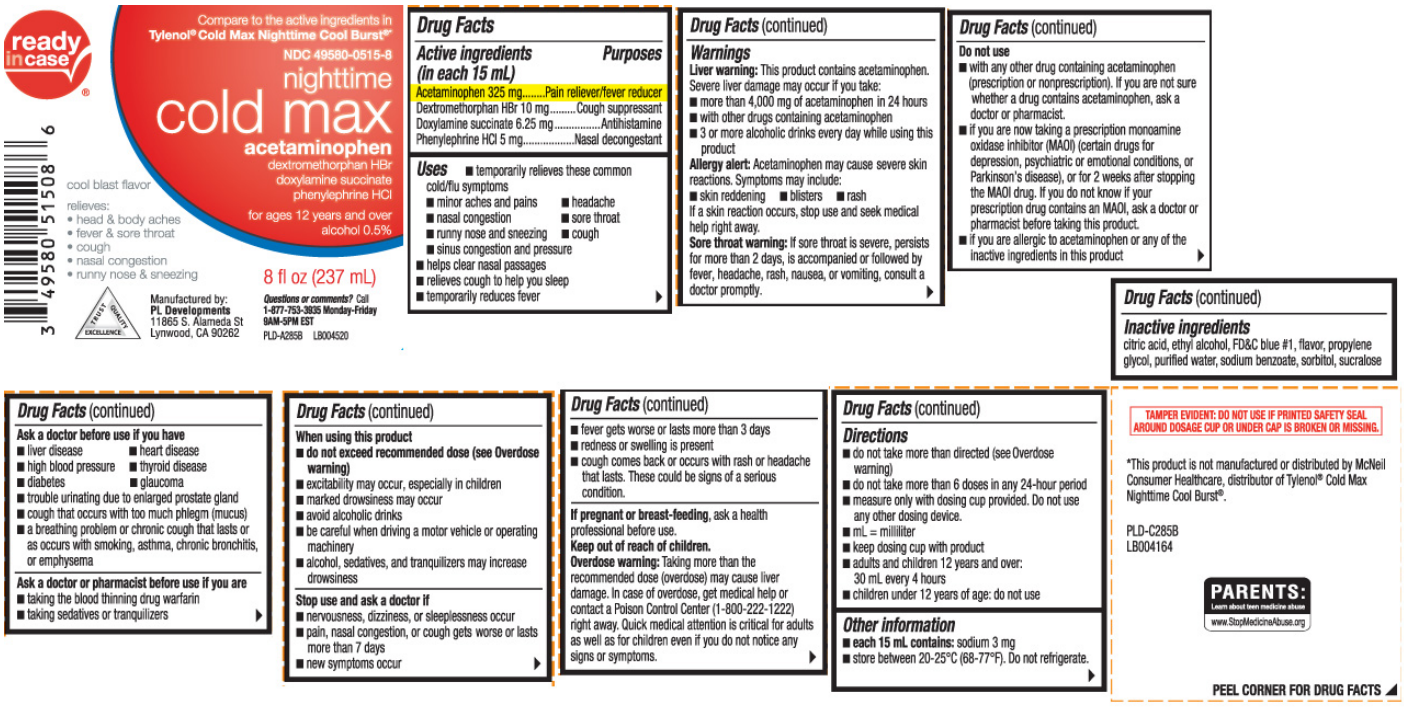
Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90262

Product Label



ReadyinCase Nighttime Cold Max Cool Blast Flavor

COLD MAX NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49580-0515
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0515-8	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/31/2016	10/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/31/2016	10/31/2024

Labeler - P & L Development, LLC (101896231)

Revised: 5/2023 P & L Development, LLC