MUCUS RELIEF NIGHTTIME COLD FLU MAXIMUM STRENGTHCOLD FLU AND SORE THROAT- acetaminophen, diphenhydramine hcl,phenylephrine hcl 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 20 mL)

Acetaminophen 650 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCL 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - runny nose
  - sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

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 daily 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 nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other drug containing diphenhydramine, even one used on the skin

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if

- you are taking the blood thinning drug warfarin
- you are taking sedatives or tranquilizers

When using this product,

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- 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 day
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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 (1800-222-1222) 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 a 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- mL = milliliter
- keep dosing cup with product
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 mL every 4 hours
- children under 12 years of age: do not use

Other information

- **each 20 mL contains:** sodium 10 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, disodium EDTA, FD&C blue #1, FD&C yellow #10, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Principal Display Panel

Compare to the active ingredients in **Maximum Strength Mucinex® Fast-Max® Clear & Cool® Night Time Cold & Flu***

max strength

night time cold & flu

Acetaminophen 650 mg Pain reliever / Fever reducer

Diphenhydramine HCL 25 mg Antihistamine/Cough suppressant

Phenylephrine HCL 10 mg Nasal decongestant

multi-symptom relief

- Relieves aches, fever & sore throat
- controls cough
- relieves nasal congestion
- relieves runny nose & sneezing

for ages 12 years & older

FL OZ (mL)

Questions or comments?

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

*This product is no manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Clear & Cool® Night Time Cold, & Flu

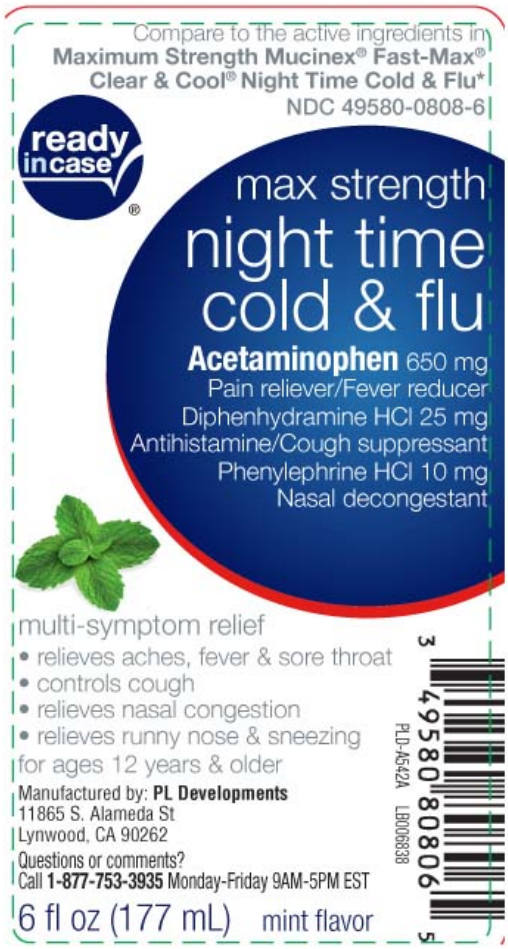
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING

Manufactured by: **PL Developments**

11865 S Alameda St

Lynwood, CA 90262

Package Label



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PLD-A542A
LB005886

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PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

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- 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.
- with any other drug containing diphenhydramine, even one used on the skin
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for

Drug Facts (continued)

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
- heart disease
- high blood pressure
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- trouble urinating due to an enlarged prostate gland
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Drug Facts (continued)

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If pregnant or breast-feeding, ask a health professional before use.

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Drug Facts (continued)

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Other information

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Inactive ingredients

citric acid, disodium EDTA, FD&C blue #1, FD&C yellow #10, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

READYinCASE Max Strength Nighttime Cold & Flu

MUCUS RELIEF NIGHTTIME COLD FLU MAXIMUM STRENGTHCOLD

FLU AND SORE THROAT

acetaminophen, diphenhydramine hcl,phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49580-0808
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT (Cool)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0808-6	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2019	12/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2019	12/31/2024

Labeler - P & L Development, LLC (101896231)

Revised: 5/2023 P & L Development, LLC