

**MUCUS RELIEF COLD AND SINUS MAXIMUM STRENGTH- acetaminophen,
guaifenesin, 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

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Expectorant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
 - minor aches and pains
 - sore throat
 - headache
 - nasal congestion
 - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

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.

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

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.
- for children under 12 years of age
- 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
- heart disease
- diabetes
- thyroid disease
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as 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.

When using this product,

do not use more than directed.

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
- 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 persistent headache. 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 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 dosing cup with other products
- dose as follows or as directed by a doctor
- mL=milliliter
- adults and children 12 years and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other information

- each 20 mL contains: **sodium 12 mg**
- store at 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

anhydrous citric acid, EDTA disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

Principal Display Panel

Compare to active ingredients in

Mucinex® Fast-Max® Maximum Strength Cold & SinusLiquid*

maximum strength

Mucus relief

cold & sinus multi-symptom relief

acetaminophen

guaifenesin

phenylephrine

- relieves headache & fever
- relieves nasal & chest congestion
- thins & loosens mucus

for ages 12 & over

Questions or comments?

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

FL OZ (mL)

Manufactured by:

PL Developments

11865 S. Alameda St

Lynwood, CA 90260

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Fast-Max® Maximum Strength Cold & Sinus Liquid

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

Package Label



Compare to active ingredients in
Mucinex® Fast-Max® Maximum
Strength Cold & Sinus Liquid*
NDC 49580-0335-9

maximum strength
mucus relief
cold & sinus
multi-symptom relief
acetaminophen
guaifenesin
phenylephrine

- relieves headache & fever
 - relieves nasal & chest congestion
 - thins & loosens mucus
- for ages 12 & over

Questions or comments?
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Monday-Friday 9AM-5PM EST



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



8 fl oz (237 mL)

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

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PLD-B281B
LBO02902

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Guaifenesin 400 mg.....	Expectorant
Phenylephrine HCl 10 mg.....	Nasal decongestant
Uses	
temporarily relieves these common cold and flu symptoms:	
■ sore throat	■ minor aches and pains
■ sinus congestion and pressure	■ nasal congestion
■ temporarily reduces fever	
■ helps loosen phlegm (mucus) and thin bronchial	

PEEL CORNER FOR MORE DRUG FACTS

PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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■ skin reddening ■ blisters ■ rash
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Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

Other information

- each 20 mL contains: sodium 12 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients anhydrous citric acid, EDTA disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum

Readyincase mucus relief cold & sinus maximum strength

MUCUS RELIEF COLD AND SINUS MAXIMUM STRENGTH

acetaminophen, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49580-0335
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49580-0335-9	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2015	12/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/28/2015	12/31/2024

Labeler - P & L Development, LLC (101896231)