

**COLD FLU AND SORE THROAT RELIEF MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Safeway, Inc.**

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

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

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

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

- 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.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

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

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

- redness or swelling is present
- nervousness, dizziness or sleeplessness occur
- new symptoms occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- 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 a 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- dose as follows or as directed by a doctor
- mL = milliliter
- adults and children 12 years of age and older: 20 mL every 4 hours while symptoms last
- children under 12 years of age: do not use

Other information

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

Inactive ingredients

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

Questions or comments?

Call **1-888-723-3929 Monday-Friday 7AM-6PM PST**

Principal Display Panel

AGES 12 & OVER

Maximum Strength

Cold, Flu & Sore Throat Relief

Acetaminophen 650 mg

-Pain Reliever - Fever Reducer

Dextromethorphan HBr 20 mg

-Cough Suppressant

Guaifenesin 400 mg

-Expectorant

Phenylephrine HCl 10 mg

-Nasal Decongestant

Relief of: fever, aches, cough, stuffy nose, mucus & chest congestion

Compare to Maximum strength Mucinex® Fast-Max® Cold, Flu & Sore Throat active ingredients*

FL OZ (mL)

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Cold, Flu & Sore Throat.

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

DISTRIBUTED BY

BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

www.betterlivingbrandsLLC.com

Package Label



Compare to
Maximum Strength
Mucinex® Fast-Max®
Cold, Flu & Sore Throat
active ingredients*

NDC 21130-036-06

MAXIMUM STRENGTH
**Cold, Flu & Sore
Throat Relief**

AGES 12 & OVER

Acetaminophen 650 mg
- Pain Reliever/Fever Reducer

Dextromethorphan HBr 20 mg
- Cough Suppressant

Guaifenesin 400 mg
- Expectorant

Phenylephrine HCl 10 mg
- Nasal Decongestant

Relieves

- Fever, Aches, Cough, Stuffy Nose
- Mucus & Chest Congestion

PLD-E282C
LB007582

6 FL OZ (177 mL)

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BETTER LIVING BRANDS LLC
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PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

Drug Facts

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PEEL CORNER FOR MORE DRUG FACTS

Drug Facts (continued)

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- cough that occurs with too much phlegm (mucus)

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Drug Facts (continued)

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Drug Facts (continued)

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PEEL CORNER FOR MORE DRUG FACTS

SIGNATURE CARE Maximum Strength Cold, Flu & Sore Throat Relief

COLD FLU AND SORE THROAT RELIEF MAXIMUM STRENGTH
acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-036
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 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)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
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)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-036-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/30/2014	

Labeler - Safeway, Inc. (009137209)

