COLD AND SINUS MAXIUM STRENGTH- acetaminophen, guaifenesin, phenylephrine hydrochloride liquid DeMoulas Market Basket

Cold & Sinus 515

Drug Facts Active ingredients (in each 20 mL)

Acetaminophen 650 mg Guaifenesin 400 mg Phenylephrine HCL 10 mg

Purpose

Pain reliever/Fever reducer Expectorant Nasal decongestant

Uses

temporarily relieves these common cold and flu symptoms:

- nasal congestion
- sinus congestion and pressure
- minor aches and pains
- sore throat
- headache
- fever
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Liver warning This product contains acetamnophen. 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 every day 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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- for children under 12 years of age

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

• taking the blood thinning product warfarin.

When using this product

· do not use more that directed

stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- redness or swelling is present
- symptoms do not get better within 7 days or are accompanied by a fever
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days, comes back, or occurs with fever, rash or persistant 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.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

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

- take only as recommended (see Overdose warning)
- use dosage cup
- mL = milliliter
- do not take more han 6 doses in any 24-hour period

Age Dose

Adults & children 20 mL every 4 hours

12 years and older

Children under 12 Do not use

years of age

Other information

- each 20 mL contains: sodium 10 mg
- dosage cup provided
- store between 15-30 C (59-86 F)
- do not refrigerate

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, Xanthan gum

Questions?

Call weekdays from 9:30 AM to 4:30 PM EST 1-877-798-5944

Cold and Sinus product label

Market Basket®
"MORE FOR YOUR MONEY"
* COMPARE TO

the active ingredients found in MUCINEX® FAST-MAX™ COLD & SINUS

Cold & Sinus
MAXIUN STRENGTH

Acetaminophen

(Pain Reliever/Fever Reducer)

Guiafenesin (Expectorant)

Phenylephrine HCL (Nasal Decongestant)

Relieves Fever & Body Aches Thins & Loosens Mucus Relieves Nasal & Chest Congestion

Adults For Ages 12 & Over

LF-009 Rev 01

6 FL OZ (177 mL)

Peel Corner to Read Completed Drug Facts and information

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

Failure to follow these warnings could result in serious consequences.

DISTRIBUTED BY DEMOULAS SUPERMARKETS INC. 875 East Street TEWKSBURY, MA 01876

* This product is not manufactured or distributed by Reckitt Benckiser Inc. distributor of Mucinex® FAST-MAX™ COLD & SINUS



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Lot: Exp:

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Drug Facts (continued)

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Drug Facts (continued)

- trouble urinating due to an enlarged prostate gland
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- phlegm (mucus) Ask a doctor or pharmacist before

use if you are taking the blood thinning drug warfarin.

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Questions?

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COLD AND SINUS MAXIUM STRENGTH

acetaminophen, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53942-515

This product is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Mucinex® FAST-MAX™ Cold & Sinus.

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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	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)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYL GALLATE (UNII: 8D4SNN7V92)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
1 NDC 25	:53942-515-	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2013	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/19/2013	
OTC Monograph Drug	M012	09/19/2013	

Labeler - DeMoulas Market Basket (007869647)

Registrant - AptaPharma Inc. (790523323)

Establishment			
Name	Address	ID/FEI	Business Operations

AptaPharma Inc. 790523323 manufacture(53942-515)

Revised: 12/2023 DeMoulas Market Basket