

**COLD, FLU AND SORE THROAT MAXIMUM STRENGTH- acetaminophen,
dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride
liquid
DeMoulas Market Basket**

**Drug Facts Active ingredients
(in each 20 mL)**

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCL 10 mg

Purpose

Pain reliever/Fever reducer
Cough suppressant
Expectorant
Nasal decongestant

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.

Uses

temporarily relieves these common cold and flu symptoms:

- cough due to minor throat and bronchial irritation
- 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 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

- **with any other drugs 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
- 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
- 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 persistent headache. These could be signs of a serious condition.

If pregnant or breast feeding

ask a health professional before use

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 dose cup
- mL = milliliter
- do not take more than 6 doses in any 24-hour period

Age - Adults and children 12 years and older Dose - 20 mL every 4 hours

Age - Children under 12 years of age Dose - Do not use

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 and C Blue #1, FD and 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 at

1-877-798-5944

Cold , Flu & Sore Throat product label

"MORE FOR YOUR DOLLAR"

MARKET BASKET

***COMPARE TO THE INGREDIENTS IN MUCINEX® FAST-MAX COLD™, FLU AND SORE THROAT**

Cold, Flu and Sore Throat

Maximum Strength

Acetaminophen
Pain Reliever/Fever Reducer

Dextromethorphan HBr
Cough Suppressant

Guaifenesin Expectorant

Phenylephrine HCL
Nasal Decongestant

Relieves Fever and Body Aches
Controls Cough
Thins and Loosens Mucus
Relieves Nasal and Chest Congestion

6 FL OZ (177mL)

Adults
For Ages 12 and Over

*This product is not manufactured or distributed by Reckitt Benckiser Inc., distributor of Mucinex® FAST-MAX™ Cold, Flu and Sore Throat.
Peel Corner to Read Complete Drug Facts and Information

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

Failure to follow these warnings could result in consequences

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

LB-008 Rev 01

Lot:
Exp:

MARKET BASKET
MORE FOR YOUR DOLLAR

*COMPARE TO
the active ingredients in
MUCINEX® FAST-MAX™
COLD, FLU & SORE THROAT

Cold, Flu & Sore Throat

MAXIMUM STRENGTH

Acetaminophen
(Pain Reliever/Fever Reducer)
Dextromethorphan HBr (Cough Suppressant)
Guaifenesin (Expectorant)
Phenylephrine HCl
(Nasal Decongestant)

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Drug Facts

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Uses temporarily relieves these common cold and flu symptoms:

- cough due to minor throat and bronchial irritation
- 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 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 ▶

Drug Facts (continued)

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.

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■ 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
■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema ▶

Drug Facts (continued)

■ 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

■ 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

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

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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. ►

Drug Facts (continued)

Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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COLD, FLU AND SORE THROAT MAXIUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53942-516
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
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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: 8D45NN7V92)	
WATER (UNII: 059QF0K00R)	
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:53942-516-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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(53942-516)

Revised: 12/2023

DeMoulas Market Basket