### MUCUS RELIEF COLD, FLU AND SORE THROAT- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated United Natural Foods, Inc. dba UNFI

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### **Equaline 44-617-CFS-Delisted**

### Active ingredients (in each caplet)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

### **Purpose**

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

#### Uses

- temporarily relieves these common cold and flu symptoms:
  - nasal congestion
  - sore throat
  - cough
  - headache
  - minor aches and pains
- 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

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

- more than 4,000 mg of acetaminophen in 24 hours
- 3 or more alcoholic drinks every day while using this product
- with other drugs containing acetaminophen

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- blisters
- rash
- skin reddening

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.
- if you have ever had an allergic reaction to this product or any of its ingredients

### Ask a doctor before use if you have

- liver disease
- diabetes
- thyroid disease
- difficulty in urination due to enlargement of the prostate gland
- heart 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)

### Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

## When using this product

do not exceed recommended dosage.

## 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
- new symptoms occur
- redness or swelling is present
- 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.

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt 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
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- use by expiration date on package

### Inactive ingredients

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

### Questions or comments?

1-855-423-2630

### Principal display panel

**EQUALINE®** 

NDC 41163-717-09

compare to
Maximum Strength
Mucinex® FAST-MAX®
Cold , Flu & Sore Throat
active ingredients\*

maximum strength mucus relief

cold, flu & sore throat

### acetaminophen

(pain reliever/fever reducer) dextromethorphan HBr (cough suppressant) guaifenesin (expectorant) phenylephrine HCl (nasal decongestant)

- relieves headache, fever & sore throat
- controls cough
- relieves nasal & chest congestion
- thins & loosens mucus

### FOR AGES 12 +

**20** caplets

actual size

TAMPER EVIDENT: DO NOT USE IF PACKAGE
IS OPENED OR IF BLISTER UNIT IS TORN,
BROKEN OR SHOWS ANY SIGNS OF TAMPERING

DOES NOT CONTAIN GLUTEN

#### **PARENTS:**

Learn about teen medicine abuse www.StopMedicineAbuse.org

DISTRIBUTED BY UNFI PROVIDENCE, RI 02908 USA

100% Quality GUARANTEED

Like it or let us make it right. **That's our quality promise.** 855-423-2630

\*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Maximum Strength Mucinex® FAST-MAX® Cold, Flu & Sore Throat.

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### MUCUS RELIEF COLD, FLU AND SORE THROAT

acetaminophen, dextromethorphan hbr, quaifenesin, phenylephrine hcl tablet, film coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-717
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)			

FD&C RED NO. 40 (UNII: WZB9127XOA)

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

STEARIC ACID (UNII: 4ELV7Z65AP)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics				
Color	red	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	44;617	
Contains				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:41163- 717-09	2 in 1 PACKAGE	12/11/2020	06/08/2025			
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	12/11/2020	06/08/2025	

# Labeler - United Natural Foods, Inc. dba UNFI (943556183)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(41163-717) , pack(41163-717)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(41163-717)

## **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(41163-717)

Revised: 6/2024 United Natural Foods, Inc. dba UNFI