**SEVERE COLD- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated**
**United Natural Foods, Inc. dba UNFI**

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**Equaline 44-503A-CMS 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:
  - sore throat
  - cough
  - nasal congestion
  - headache
  - minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

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

**Ask a doctor before use if you have**

- heart disease
- liver disease
- diabetes
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- thyroid disease
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- high blood pressure

**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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- 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 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**
- adults and children 12 years and over
  - take 2 caplets every 4 hours
  - swallow whole - do not crush, chew, or dissolve
  - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

***Other information***

- **each caplet contains:** sodium 3 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

***Inactive ingredients***

corn starch, crospovidone, D&C yellow #10 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

***Questions or comments?***

**1-855-423-2630**

***Principal Display Panel***

**EQUAL**INE®

NDC 41163-053-08

**multi-symptom**
**severe cold**
**acetaminophen**
(pain reliever/fever reducer)
dextromethorphan HBr
(cough suppressant)
guaifenesin
(expectorant)
phenylephrine HCl
(nasal decongestant)

*relieves:*
• *headache & fever*
• *sore throat*
• *nasal congestion*
• *cough & mucus*

**24** 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**

50844 REV0922D50308

**DISTRIBUTED BY UNFI, PROVIDENCE, RI 02908 USA**
**100% Quality Guaranteed**
855-423-2630

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org


**Equaline 44-503**

# SEVERE COLD

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

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:41163-053 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (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) | |
| **D&C YELLOW NO. 10 ALUMINUM LAKE** (UNII: CQ3XH3DET6) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | OVAL | **Size** | 19mm |
| **Flavor** | MENTHOL | **Imprint Code** | 44;503 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:41163-053-08 | 2 in 1 CARTON | 01/27/2023 | 11/30/2026 |
| **1** | | 12 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 | 01/27/2023 | 11/30/2026 |

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

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | manufacture(41163-053) , pack(41163-053) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | manufacture(41163-053) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 117025878 | manufacture(41163-053) |

Revised: 5/2025

United Natural Foods, Inc. dba UNFI