

MIXED BERRY SORE THROAT AND COUGH LOZENGE- benzocaine lozenge
United Natural Foods, Inc. dba UNFI

Benzocaine 7.5 mg
Dextromethorphan hydrobromide 5 mg

Active ingredients (in each lozenge)

Benzocaine 7.5 mg

Dextromethorphan hydrobromide 5 mg

Purposes

Oral pain reliever

Cough suppressant

Uses temporarily relieves these symptoms:

occasional minor mouth irritation, sore mouth and sore throat

cough due to minor throat and bronchial irritation as may occur with the common cold

Warnings

Methemoglobinemia warning:

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Sore throat warnings: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea or vomiting consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsens, see your dentist or doctor promptly.

Allergy alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

Do not use 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 teething
- in children under 2 years of age

Ask a doctor before use if you have:

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

Stop use and ask doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling develops
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness

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 Poison Control Center right away.

Directions

adults and children 12 years and older - allow 2 lozenges to dissolve in mouth, one at a time; may be repeated every 4 hours, not to exceed 12 lozenges in 24 hours, or as directed by a doctor

children 6 to 12 years of age - take 1 lozenge and allow to dissolve slowly in the mouth; may be repeated every 4 hours, not to exceed 6 lozenges in 24 hours, or as directed by a doctor

children under 6 years of age - do not use

Other information

- store at room temperature
- protect from moisture

Inactive ingredients: Acesulfame potassium, corn starch, corn syrup, FD&C blue no. 1, FD&C red no. 40, glycerin, medium chain triglycerides, natural and artificial flavors, propylene glycol, soybean oil, sucrose and water.

Questions? Or to report an adverse event call **1-877-932-7948**



MIXED BERRY SORE THROAT AND COUGH LOZENGE

benzocaine lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41163-021 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|----------|
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 5 mg |
| BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) | BENZOCAINE | 7.5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | red | Score | no score |
| Shape | ROUND | Size | 17mm |
| Flavor | BERRY | Imprint Code | B |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:41163-021-18 | 18 in 1 BLISTER PACK; Type 0: Not a Combination Product | 10/16/2015 | |



Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 10/16/2015 | |

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

Registrant - Bestco Inc. (002149136)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
| Bestco Inc. | | 002149136 | manufacture(41163-021) |

Revised: 1/2024

United Natural Foods, Inc. dba UNFI