

CHERRY SORE THROAT RELIEF LOZENGE- benzocaine lozenge
Valu Merchandisers Company

Benzocaine 15 mg
Menthol 3.6 mg

Active ingredients (in each lozenge)

Benzocaine 15 mg

Menthol 3.6 mg

Purpose

Oral anesthetic

Oral anesthetic

Uses temporarily relieves these symptoms:

occasional minor irritation, pain, sore mouth and sore throat

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 warning: 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 persists 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

- for teething
- in children under 2 years of age

Stop use and ask doctor if

- sore throat is severe or irritation, pain or redness persists or worsens
- sore mouth symptoms do not improve in 7 days

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 5 years and older - allow 1 lozenge to dissolve slowly in mouth. May be repeated every 2 hours as necessary or as directed by a doctor.

children under 5 years - do not use

Inactive ingredients: Corn starch, FD&C red no. 40, glucose syrup, glycerin, medium chain triglycerides, natural and artificial flavors, propylene glycol, soybean oil, sucrose and water.

Questions? Or to report an adverse event call **1-800-245-2898**. Monday through Friday, 9AM - 4PM EST





■
Cyan

■
Magenta

■
Yellow

■
Black

■
PMS 215 C

■
Die

■
No Coat

JOB NAME: 23182_300139001t.art
 JOB NUMBER: LF434
 Date: 8/20/13 1:56 PM Tech JM

Laser Inkjet BlueLine Waterproof Epson
 OK to run as is

Make corrections; submit new proof
 Make corrections; no new proof is required

Signature _____

Return this proof promptly to meet your delivery requirements. Please notify us if a delay is anticipated. Return all materials with proof.

Proof must be returned to Chesapeake Pharmaceutical and Healthcare Packaging by ____/____/____ am pm In order to ensure on time delivery.

CHERRY SORE THROAT RELIEF LOZENGE
 benzocaine lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63941-047 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5) | BENZOCAINE | 15 mg |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 3.6 mg |

Inactive Ingredients

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

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:63941-047-18 | 18 in 1 BLISTER PACK; Type 0: Not a Combination Product | 08/28/2013 | |



Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 08/28/2013 | |

Labeler - Valu Merchandisers Company (868703513)

Registrant - Bestco Inc. (002149136)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Bestco Inc. | | 002149136 | manufacture(63941-047) |