

MENTHOL COUGH DROPS- menthol lozenge

Freds

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Menthol 5.4 mg

Active ingredient (in each drop)

Menthol 5.4 mg

Purpose

Cough suppressant / Oral anesthetic

Uses temporarily relieves:

cough as may occur with a cold

occasional minor irritation and sore throat

Warnings

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, see your dentist or doctor promptly. These symptoms may be serious.

Ask a doctor before use if you have:

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

cough accompanied by excessive phlegm (mucus)

Stop use and ask doctor if

cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

sore throat is severe, or irritation, pain or redness lasts or worsens

sore mouth does not improve in 7 days

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

Keep out of reach of children.

Directions

adults and children 5 years and over - dissolve 1 lozenge slowly in mouth. Repeat every 2 hours as needed or as directed by a doctor.

children under 5 years - ask a doctor

Other information

10 calories per drop

Inactive ingredients: Corn starch, corn syrup, eucalyptus oil, FD&C blue no. 1, FD&C red no. 40, glycerin, gum arabic, medium chain triglycerides, natural flavor, potassium sorbate, soybean oil, sucrose and water.

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

EXPLORE THE WORLD OF HEALTH CARE

Do not use if bag
is torn or open

Resealable Bag

← Tear here

Tear here →

1. Tear here 2. Separate to open 3. Press to reseal

fred's[®]

Menthol Cough Drops [®]

Menthol Cough Suppressant /
Oral Anesthetic

- Soothes Sore Throats
- Temporarily Relieves Coughs



freds

LAB TESTED

Lab Tested for Quality,
Fred Tested for Satisfaction

40 Drops

Compare To The Active Ingredient in

**Halls®
Cough Drops***



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freds Promise
Not Happy With This Product?
Just Bring It Back For a Refund!

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Gluten-Free



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Ask a doctor before use if you have:

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- cough accompanied by excessive phlegm (mucus)

Stop use and ask doctor if

- cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore throat is severe, or irritation, pain or redness lasts or worsens
- sore mouth does not improve in 7 days

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

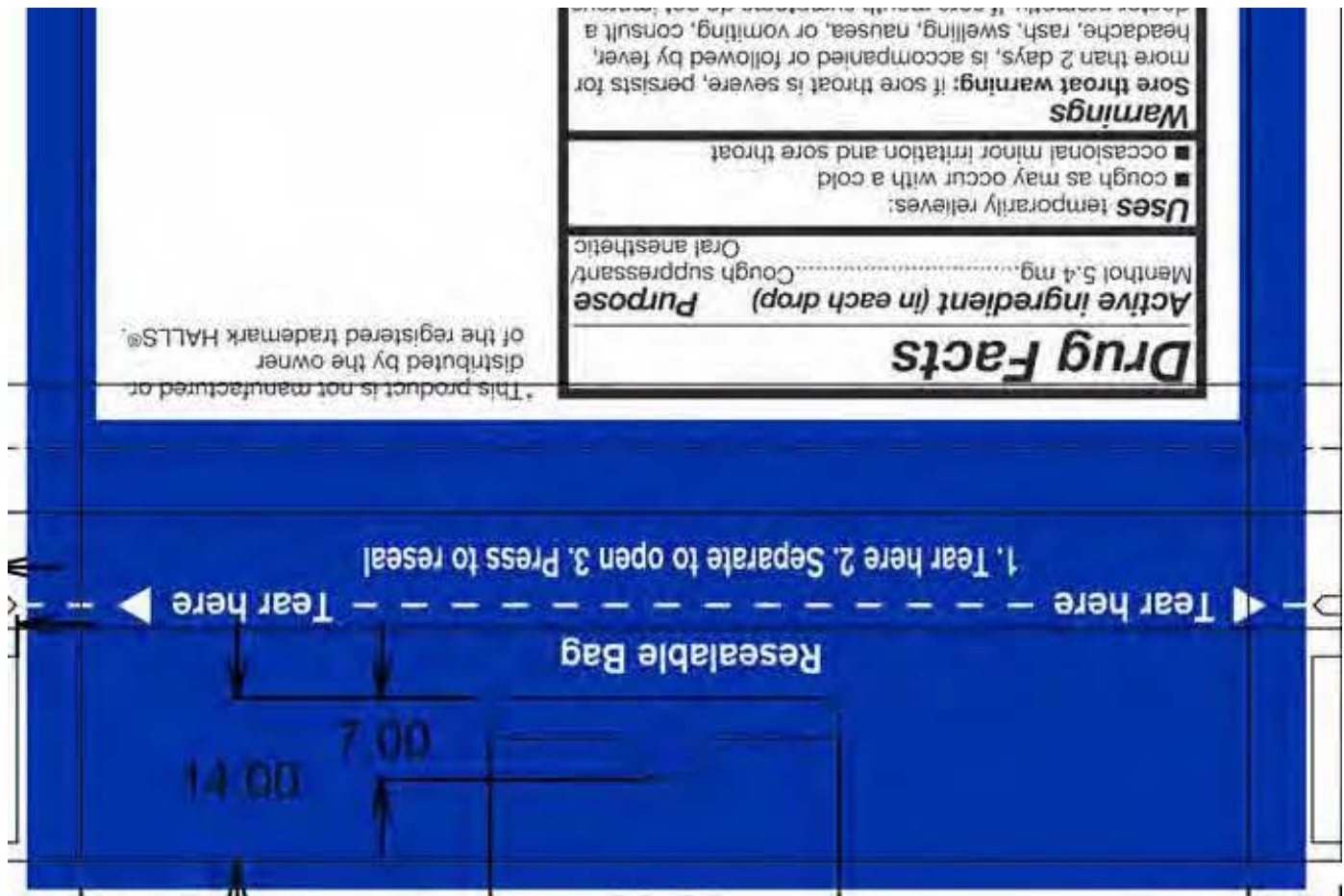
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| | |
|------------------------|--|
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MENTHOL COUGH DROPS

menthol lozenge

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55315-029 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5.4 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--------------------------|----------|
| WATER (UNII: 059QF0K00R) | |

Product Characteristics

| | | | |
|----------|------------------------------------|--------------|----------|
| Color | blue (Light Blue with Blue Flakes) | Score | no score |
| Shape | OVAL | Size | 17mm |
| Flavor | MENTHOL | Imprint Code | B |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:55315-029-40 | 40 in 1 BAG; Type 0: Not a Combination Product | 01/09/2018 | |



Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 01/09/2018 | |

Labeler - Freds (005866116)

Registrant - Bestco Inc. (002149136)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Bestco Inc. | | 002149136 | manufacture(55315-029) |

