### SUGAR FREE MENTHOL COUGH DROPS- menthol lozenge American Sales

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 5.8 mg

## Active ingredient (in each drop)

Menthol 5.8 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 - allow 1 drop to dissolve slowly in mouth. May be repeated every 2 hours as necessary or as directed by a doctor.

children under 5 years - ask a doctor

#### Other information

- 6 calories per drop
- Excess consumption may cause a laxative effect.

Inactive ingredients: Acesulfame potassium (non-nutritive sweetener), corn starch,

eucalyptus oil, FD&C blue no. 1, FD&C red no. 40, glycerin, gum arabic, hydrogenated starch hydrolysate, isomalt, medium chain triglycerides, natural and artificial flavors, potassium sorbate, soybean oil, sucralose (non-nutritive sweetener) and water.

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





Questions? Or to report an adverse event call

soybean oil, sucralose (non-nutritive sweetener), water, triglycerides, natural and artificial flavors, potassium sorbate, hydrogenated starch hydrolysate, isomalt, medium chain blue no. 1, FD&C red no. 40, glycerin, gum arabic, (non-nutritive sweetener), corn starch, eucalyptus oil, FD&C Inactive ingredients: acesultame potassium

 Excess consumption may cause a laxative effect. Other information = 6 calories per drop

> I ask a doctor children under 5 years

or as directed by a doctor.

5 years and over adults and children

ea

every two hours as necessary in mouth. May be repeated silow 1 drop to dissolve slowly

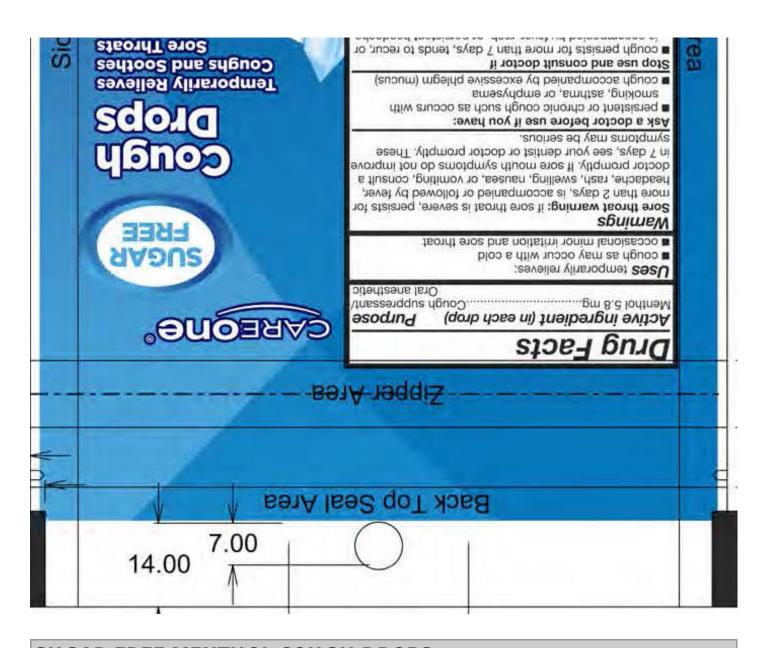
Directions

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

- sore mouth does not improve in 7 days
- sore throat is severe, or irritation, pain or redness lasts These could be signs of a serious condition. is accompanied by rever, rash, or persistent neadache



Seal Area



# **SUGAR FREE MENTHOL COUGH DROPS**

menthol lozenge

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-020

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
9		

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL 5.8 mg

#### **Inactive Ingredients**

Ingredient Name	Strength
-----------------	----------

WATER (UNII: 059QF0KO0R)

Product Characteristics			
Color	blue (light blue with blue flakes)	Score	no score
Shape	OVAL	Size	16mm
Flavor	MENTHOL	Imprint Code	В
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:41520-020- 25	25 in 1 BAG; Type 0: Not a Combination Product	06/22/2016	



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/22/2016	

# Labeler - American Sales (809183973)

# Registrant - Bestco Inc. (002149136)

Establishment			
Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(41520-020)

Revised: 10/2023 American Sales