SUGAR FREE MENTHOL COUGH DROPS- menthol lozenge Topco Associates

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 5.8mg

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 occcurs 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.

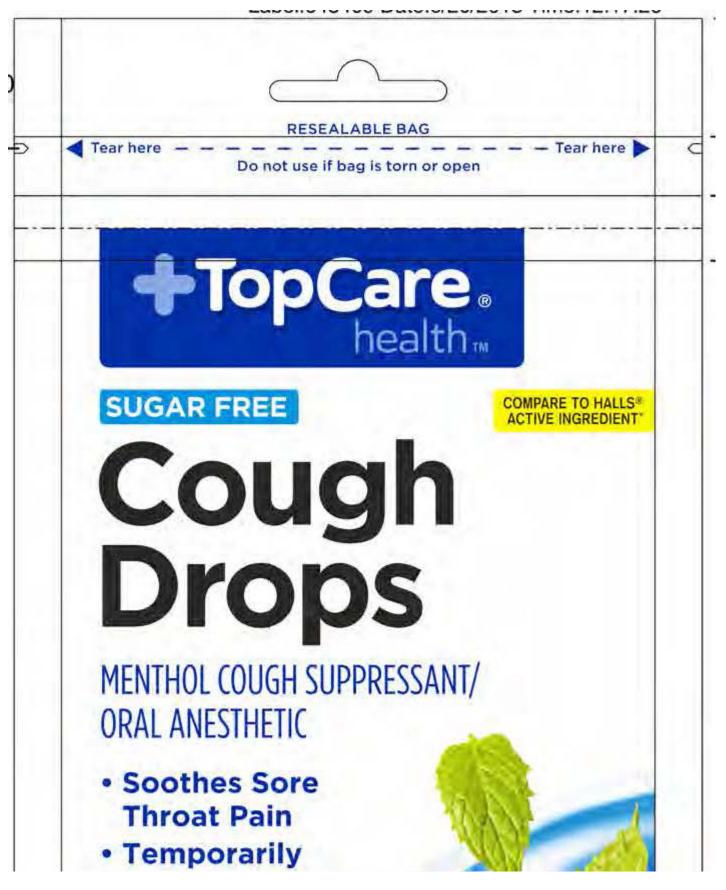
children under 5 years - ask a doctor

Other information

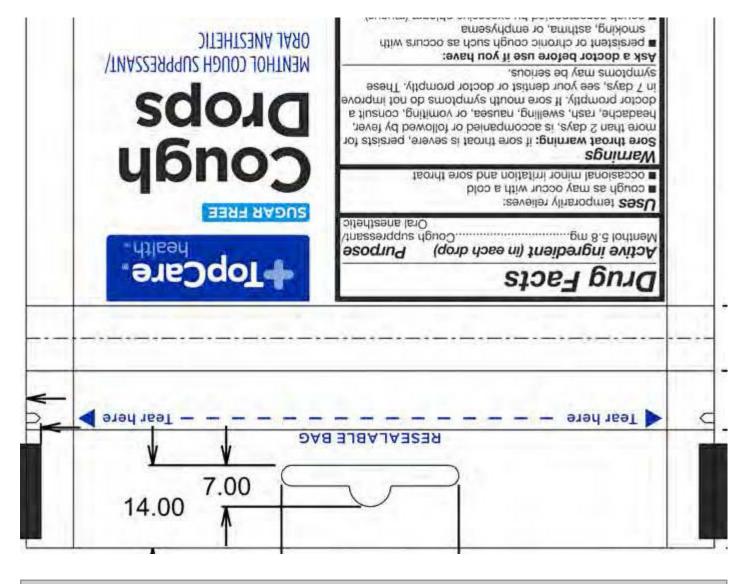
- 6 calories per drop
- Excess consumption may cause a laxative effect.

Inactive ingredients: Acesulfame potassium, corn starch, eucalyptus oil, FD&C blue no. 1, FD&C red no. 40, glycerin, gum arabic, isomalt, maltitol syrup, medium chain triglycerides, natural and artificial flavors, potassium sorbate, soybean oil, sucralose and water.

Questions? Or to report an adverse event call 1-888-423-0139.







SUGAR FREE MENTHOL COUGH DROPS

menthol lozenge

mendionozenge						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		e)	NDC:36800-819	
Route of Administration	ORAL					
Active Ingredient/Active	Moiety					
Ingredient Name			Basis of Strength		gth	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)			MENTHOL			5.8 mg
lus stive lusure disets						
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			
Packaging			
		Marketing Start	Marketing End
# Item Code		Date	Date
1 NDC:36800-819- 25	 25 in 1 BAG; Type 0: Not a Combination Product 	03/22/2013	
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Markoting	Information		
	Information		
Marketing Category	Application Number or Monogra Citation	oh Marketing Start Date	Marketing End Date
OTC monograph fir		03/22/2013	
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Labeler - Topco Associates (006935977)

Establishment							
Name	Address	ID/FEI	Business Operations				
Bestco Inc.		002149136	manufacture(36800-819)				
Desico Inc.		002149130	manufacture(50000-019)				

Revised: 10/2023

Topco Associates