SUGAR FREE COUGH DROPS- menthol pastille Topco Associates LLC

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.

Sugar Free Cough Drops

Active ingredient 7.6 mg
Cough Suppressant
Oral anesthetic

RESEALABLE BAG





SUGAR FREE

Cough Drops

MENTHOL COUGH SUPPRESSANT/ORAL ANESTHETIC

COMPARE TO HALLS® ACTIVE INGREDIENT

Coathac Care Threat Dain



Uses temporarily relieves:

- cough as may occur with a cold
- ocassional minor irritation and sore throat

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Warnings

Sore throat warning: severe or persistence sore throat accompanied by high fever, headache, nausea and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children under 12 years of age.

Ask a doctor before use if you have

- a severe throat accompanied by difficulty in breathing or that last more than 2 days
- a sore throat accompanied by fever, headache, rash, swelling, nausea or vomiting

Stop use and consult a doctor if

• sore mouth symptons do not improve in 7 days or if irritation, pains or redness persists or worsens.

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

Keep this and all drugs out of the reach of children.

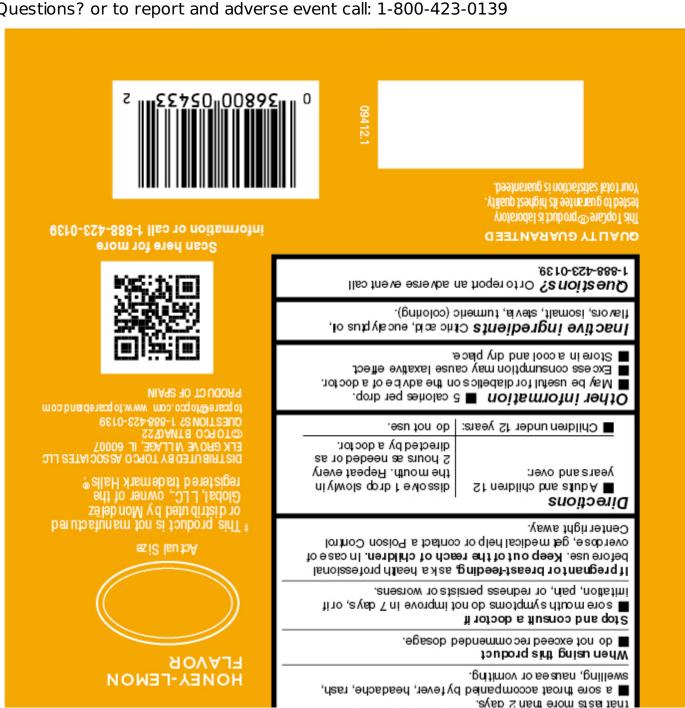
In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years and over: dissolve 1 drop slowly in mouth. Repeated every 2 hours as needed or as directed by a doctor.
- Children under 12 years and under do not use
- 5 calories per drop
- Store in a cool and dry place
- Maybe useful for diabetics on the advice of doctors
- Excess consumption may cause laxative effect

citric acid, isomalt, stevia

Questions? or to report and adverse event call: 1-800-423-0139



 a severe cough accompanied by difficulty in breathing or Ask a doctor before use if you have

than 2 days or administer to children under 12 years of age. may be serious. Consult doctor promptly. Do not use more accompanied by high fever, headache, nausea, and vomiting Sore throat warning: Severe or persistent sore throat Marnings

> occasional minor irritation and sore throat. cough as may occur with a cold. USes temporarily relieves:

Menthol 7.6 mg cough suppressant, oral anerthetic Active ingredient (in each drop) səs odın_d

Drug Facts



SUGAR FREE

Sweetened with Stevia

No Synthetic Colors

• No Artificial Flavors

& Temporarily Relieves

Soothes Sore Throat Paln

MENTHOL COUGH SUPPRESSANT/

or Preservatives

Condh

ORAL ANESTHETIC

Tearhere 🕨

RESEALABLE BAG

SUGAR FREE COUGH DROPS

menthol pastille

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-013
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.8 mg

Inactive Ingredients				
Ingredient Name	Strength			
EUCALYPTUS OIL (UNII: 2R040NI662)				
TURMERIC (UNII: 856YO1Z64F)				
ISOMALT (UNII: S870P55O2W)				
STEVIOL (UNII: 4741LYX6RT)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				

Product Characteristics				
Color	yellow	Score	score with uneven pieces	
Shape	OVAL	Size	25mm	
Flavor	HONEY (Lemon)	Imprint Code	None	
Contains				

l	P	ackaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:76162-013- 01	25 in 1 BAG; Type 0: Not a Combination Product	12/14/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	12/14/2022		

Labeler - Topco Associates LLC (006935977)

Registrant - Boston Nutraceutical Science SL (466061824)

Establishment				
Name	Address	ID/FEI	Business Operations	
Boston Nutraceutical Production SL		468121064	label(76162-013) , pack(76162-013) , manufacture(76162-013)	

Revised: 12/2022 Topco Associates LLC