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.

Menthol Cough Drops

Active ingredient 5.8 mg
Cough Suppressant
Oral anesthetic

RESEALABLE BAG

Tear here



SUGAR FREE COUGH Drops MENTHOL COUGH SUPPRESSANT/ORAL ANESTHETIC COMPARE TO HALLS® ACTIVE INGREDIENT*



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

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
- Store in a cool and dry place

citric acid, isomalt, stevia

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



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 5.8 mg cough suppressant, oral anesthetic Active ingredient (in each drop) səso dın d

Drug Facts



TopCar

MENTHOL COUGH SUPPRESSANT/ Drops **SUGAR FREE**

Colors, Flavors

& Temporarily Relieves

Soothes Sore Throat Paln

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ORAL ANESTHETIC

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Tear here

RESEALABLE BAG

SUGAR FREE COUGH DROPS

menthol pastille

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-010
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	
ISOMALT (UNII: S870P55O2W)		
STEVIOL (UNII: 4741LYX6RT)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		

Product Characteristics			
Color	white (Transparent)	Score	score with uneven pieces
Shape	OVAL	Size	25mm
Flavor	MENTHOL	Imprint Code	None

Contains

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:76162-010- 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(76162-010) , pack(76162-010) , manufacture(76162-010)	

Revised: 12/2022 Topco Associates LLC