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.

Cough Drops

Active ingredient 5.4 mg

Cough Suppressant

Oral anesthetic

RESEALABLE BAG





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

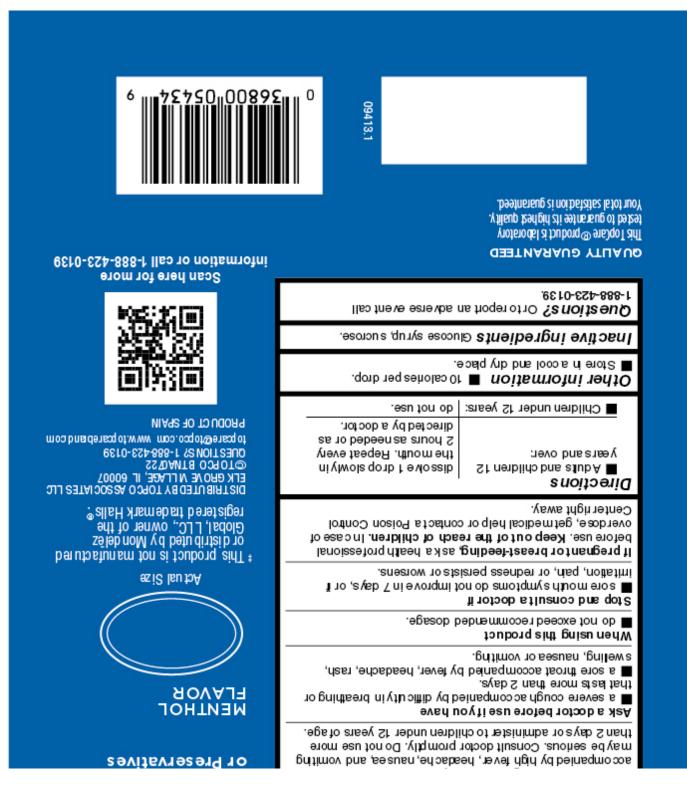
away.

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
- Store in a cool and dry place

glucose syrup, sucrose

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



Sore throat warning: Severe or persistent sore throat sgninnaW

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

Menthol 5.4 mg cough suppressant, oral anesthetic (qonb na se ni) traibangni avitaA səsodund

RESEALABLE BAG

Drug Facts

health •TopCare.

Colors, Flavors Isioifith A oN

46noo & Temporarlly Relleves Soothes Sore Throat Pain

ORAL ANESTHETIC MENTHOL COUGH SUPPRESSANT/

Drops **ybno**j



menthol past	tille							
Product In	formation							
Product Typ	e	HUMAN OTC DF	RUG	Item Code (Source) ND		NDC:	DC:76162-011	
Route of Ad	ministration	ORAL						
A . I . I . I		NA - 1 - 1						
Active Ingi	redient/Active	-						
Ingredient Name					Basis of Strength		Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)					MENTHOL		5.4 mg	
inactive in	gredients							
Inactive In	-	igredient Na	me			Str	ength	
	-	igredient Na	me			Stre	ength	
SUCROSE (UN	Ir	igredient Na	me			Stre	ength	
SUCROSE (UN	Ir II: C151H8M554)	igredient Na	me			Str	ength	
SUCROSE (UN CORN SYRUP	ir II: C151H8M554) (UNII: 9G5L16BK6N)	igredient Na	me			Str	ength	
SUCROSE (UN CORN SYRUP Product Cl	Ir II: C151H8M554) (UNII: 9G5L16BK6N) haracteristics		Score		score with			
SUCROSE (UN CORN SYRUP Product Cl Color	ir II: C151H8M554) (UNII: 9G5L16BK6N)				score with 25mm	Stro uneven piece		
SUCROSE (UN CORN SYRUP	Ir II: C151H8M554) (UNII: 9G5L16BK6N) haracteristics white (Transpar		Score	ode				

Packaging								
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:76162-011- 01 30 in 1 BAG; Type 0: Not a Combination Product 12/14/2022							
M	larketing I	nformation						
M	larketing l Marketing Category	nformation Application Number or Monograph Citation	n Marketing Start Date	Marketing End Date				

Labeler - Topco Associates LLC (006935977)

Registrant - Boston Nutraceutical Science SL (466061824)

Establishment								
Name	Address	ID/FEI	Business Operations					
Boston Nutraceutical Production		468121064	label(76162-011) , pack(76162-011) , manufacture(76162- 011)					

Revised: 12/2022

Topco Associates LLC