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 7.5 mg
Cough Suppressant
Oral anesthetic

RESEALABLE BAG





Cough Drops

MENTHOL COUGH SUPPRESSANT/ORAL ANESTHETIC

COMPARE TO HALLS® ACTIVE INGREDIENT[‡]

Soothor Soro Throat 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

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
- 10 calories per drop

citric acid, honey, flavors, glucose syrup, sucrose, turmeric

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



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Uses temporarily relieves:

Active ingredient (in each drop) Purposes

Menthol 7.5 mg cough suppressant, oral anethotic

Drug Facts



 No Artificial Flavors, Preservatives

Soothes Sore Throat Pain & Temporarily Relieves Cough

MENTHOL COUGH SUPPRESSANT/ ORAL ANESTHETIC



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RESEALABLE BAG

COUGH DROPS

menthol pastille

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76162-015

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)

MENTHOL

5.8 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
SUCROSE (UNII: C151H8M554)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HONEY (UNII: Y9H1V576FH)	
TURMERIC (UNII: 856YO1Z64F)	

Product Characteristics

Color	yellow	Score	score with uneven pieces
Shape	OVAL	Size	25mm
Flavor	HONEY	Imprint Code	None
Contains			

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	9	9

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76162-015- 01	30 in 1 BAG; Type 0: Not a Combination Product	12/14/2022	

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC monograph finalpart34112/14/2022

Labeler - Topco Associates LLC (006935977)

Registrant - Boston Nutraceutical Science SL (466061824)

Establishment				
Name	Address	ID/FEI	Business Operations	
Boston Nutraceutical Production SL		468121064	label(76162-015) , pack(76162-015) , manufacture(76162-015)	

Revised: 12/2022 Topco Associates LLC