

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 5.8 mg

Cough Suppressant

Oral anesthetic

RESEALABLE BAG

Tear here ►



Cough Drops

MENTHOL COUGH SUPPRESSANT/ORAL ANESTHETIC

COMPARE TO HALLS® ACTIVE INGREDIENT†

Soothes Sore Throat Pain
& Temporarily Relieves Cough

- No Artificial Flavors, Preservatives or Sweeteners
- No Synthetic Colors



80 DROPS

CHERRY FLAVOR

Uses temporarily relieves:

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

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- occasional minor irritation and sore throat

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 symptoms 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
- 10 calories per drop

citric acid, black currant, black carrot, flavors, glucose syrup, sucrose

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



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Scan here for more information or call 1-888-423-0139



Drug Facts

Active ingredient (in each drop) Purposes
Menthol 5.8 mg cough suppressant, oral anesthetic

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

Warnings
 Sore throat warning: Severe or persistent sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult 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 cough accompanied by difficulty in breathing or that lasts more than 2 days.
 ■ a sore throat accompanied by fever, headache, rash, swelling, nausea or vomiting.

When using this product
 ■ do not exceed recommended dosage.
 ■ Stop and consult a doctor if:
 ■ sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens.

If pregnant or breast-feeding, ask a health professional before use. **Keep out of the reach of children.** In case of 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 the mouth. Repeat every 2 hours as needed or as directed by a doctor.
 ■ Children under 12 years: do not use.

Other information ■ 10 calories per drop.
 ■ Store in a cool and dry place.

Inactive ingredients Biscourant and bicarrot extract (coloring), citric acid, flavors, glucose syrup, sucrose.

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

QUALITY GUARANTEED
 This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

09417.1

COUGH DROPS
 menthol pastille

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-016
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
CORN SYRUP (UNII: 9G5L16BK6N)	
SUCROSE (UNII: C151H8M554)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BLACK CURRANT (UNII: 9755T40D11)	
BLACK CARROT (UNII: 27793ZFD2L)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-016-01	80 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(76162-016) , pack(76162-016) , manufacture(76162-016)

