MENTHOL COUGH DROPS- menthol pastille Boston Nutraceutical Production SL

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 Sugar Free Sweetened with Stevia Extract 36 drops

Active Ingredient in each drop Purposes

Menthol 5.8 mg

Cough Suppressant

Oral anesthetic

Resealable Bag

1. Tear 2. Separate to open 3. Press to reseal



Compare to the active ingredients in Halls®‡

SUGAR FREE
Sweetened with Stevia Extract



Cough Drops

MENTHOL COUGH SUPPRESSANT Oral Anesthetic

Temporarily relieves cough & soothes sore throats.

Soothing Relief

Menthol Flavor

*Actual Size Depiction on Back

36 DROPS

Purposes

Cough suppressant/

Oral anesthetic

Uses Temporarily relieves:

- cough as may occur with cold or inhaled irritants
- ocassional minor irritations and sore throat

Warnings

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swealing, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptons may be serious.

Ask a doctor before use if you have

persistent or chronic cough such as occurs with smoking, asthma, or emphysema

cough accompanied by excessvie phlegm (mucus)

Stop use and consult doctor if

- cough persists for more than 7 days, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore throat is severe, or irritation, pain or redness last or worsens

• sore mouth does not improve in 7 days

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 5 years and over: allow 1 drop to dissolve slowly in mouth. May be repeated every two hours as necessary or as directed by a doctor.
- Children under 5 years: ask a doctor

Other information

- 6 calories per drop
- May be useful for diabetics on the advise of a doctor
- Excessive consumption may cause laxative effect

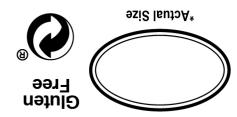
Isomalt, stevia, water

UPC FPO

LOT / EXP. DATE

owner of the registered trademark Halls®

Distributed by: Boston Nutraceutical Science LLC. 75 Arlington Street Suite 500. Boston, MA 02116. PRODUCT OF SPAIN. Questions or Comments call 617-848-4560



Inactive ingredients: Isomalt, stevia. ■ Excess consumption may cause laxative effect. May be useful for diabetics on the advise of a doctor. ■ 6 calories per drop. Uther intormation Children under 5 years: ask a doctor. a doctor. necessary or as directed by repeated every two hours as slowly in mouth. May be years and over: allow 1 drop to dissolve Adults and children 5 DIrections Center right away. overdose, get medical help or contact a Poison Control

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.

- lasts or worsens. ■ sore mouth does not improve in 7 days.
- saccompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
 sore throat is severe, or irritation, pain or redness
 - cough persists for more than / days, tends to recur,
 - When using this product do not exceed recommended dosage.

condp sccompanied by excessive phlegm (mucus).

Soothing Relief

■ Persistent or chronic cough such as occurs with

Varinings
Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. These symptoms may be serious.

- occasional minor irritation and sore throat.
- **Uses** temporarily relieves:

 cough as may occur with a cold or inhaled irritants.

Oral anesthetic

Drug Facts

Temporarily relieves cough & soothes sore throats.

MENTHOL COUGH SUPPRESSANT Oral Anesthetic

Menthol Cough Drops

Sugar Free



	3. Press to reseal	2. Separate to open	1. Tear
езк реке Þ — — -	 Bag	Resealable	◀ Tear here



Questions or comments call: 617-848-4560

-- ◀ Tear here ---- Resealable Bag

1. Tear 2. Separate to open 3. Press to reseal





SUGAR FREE Sweetened with Stevia Extract

Menthol

Cough Drops

MENTHOL COUGH SUPPRESSANT Oral Anesthetic

Temporarily relieves cough & soothes sore throats.

Soothing Relief

Menthol Flavor

*Actual Size Depiction on Back

36 DROPS

MENTHOL COUGH DROPS

menthol pastille

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:72628-105

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)				
WATER (UNII: 059QF0KO0R)				
STEVIA REBAUDIANA WHO LE (UNII: 6U422Y08O2)				

Product Characteristics					
Color	blue (Light blue)	Score	score with uneven pieces		
Shape	OVAL	Size	17mm		
Flavor	MENTHOL	Imprint Code	None		
Contains					

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:72628-105-01	36 in 1 BAG; Type 0: Not a Combination Product	03/26/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	03/26/2019		

Labeler - Boston Nutraceutical Production SL (468121064)

Registrant - Boston Nutraceutical Science SL (466061824)

Establishment				
Name	Address	ID/FEI	Business Operations	
Boston Nutraceutical Production SL		468121064	manufacture(72628-105), label(72628-105), pack(72628-105)	

Revised: 1/2021 Boston Nutraceutical Production SL