

MENTHOL COUGH DROPS- menthol pas tille
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

150 drops

Active Ingredient in each drop Purposes

Menthol 5.8 mg

Cough Suppressant

Oral anesthetic

Resealable Bag

--- ◀ Tear here --- --- ▶ Tear here ---

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



Compare to the active ingredients in Halls®†

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

150 DROPS

Purposes

Cough suppressant/

Oral anesthetic

Uses Temporarily relieves:

- cough as may occur with cold or inhaled irritants
- occasional 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, sweating, 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.

Ask a doctor before use if you have

persistent or chronic cough such as occurs with smoking, asthma, or emphysema
cough accompanied by excessive 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 advice of a doctor
- Excessive consumption may cause laxative effect

Isomalt, stevia, water

Resealable Bag

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Drug Facts	
Active ingredient (in each drop)	Purposes
Menthol 5.8 mg	Cough suppressant / Oral anesthetic
Uses temporarily relieves:	
<ul style="list-style-type: none"> ■ cough as may occur with a cold or inhaled irritants. ■ occasional minor irritation and sore throat. 	
Warnings	
<p>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.</p>	
<p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema. ■ cough accompanied by excessive phlegm (mucus). 	
<p>When using this product</p> <ul style="list-style-type: none"> ■ do not exceed recommended dosage. 	
<p>Stop use and consult doctor if</p> <ul style="list-style-type: none"> ■ 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 lasts or worsens. ■ sore mouth does not improve in 7 days. 	
<p>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.</p>	
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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.
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Inactive ingredients: Isomalt, stevia.	



Sugar Free

Menthol
Cough Drops

MENTHOL COUGH SUPPRESSANT
Oral Anesthetic

Temporarily relieves cough & soothes sore throats.

Soothing Relief



*Actual Size

Gluten Free



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

‡ This product is not manufactured or distributed by the owner of the registered trademark Halls®.

Leave blank for
LOT / EXP. DATE

00218

UPC FPO

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150 DROPS

MENTHOL COUGH DROPS

menthol pastille

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72628-106
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 WHOLE (UNII: 6U422Y08O2)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72628-106-01	150 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(72628-106) , label(72628-106) , pack(72628-106)