# NATURAL HERBAL COUGH DROPS- menthol pastille BOSTON NUTRACEUTICAL PRODUCTION, S.L

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.

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Natural Herbal Cough Drops Cough Suppressant Oral Anesthetic

## **Active Ingredient in each drop Purposes**

Menthol 4.8 mg

Cough Suppressant

Oral Anesthetic

Purposes

Temporarily relieves:

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

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## Warnings

Sore throat warning: is sore throat is severe, persist for more than 2 days, is accompanied or followed by fever headache, rash, swelling, nausea and vomiting maybe serious consult a doctor promptly. If sore mouth symptons 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 ephysema.
- Cough accompanied by excessive pleghm (mucus)

Stop use and consult doctor if

- cough persist for more than 7 days or tends to recur or is accompanied by fever, rash or persistent headache. These could be signs of a serious conditions
- sore throat is severe or irritation, pain or redness lasts 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 6 years and over: allow 2 drops to dissolve slowly in mouth one at a time. Maybe repeated every two hours as needed or as directed by a doctor.
- Children under 6 years ask a doctor

## Other information

- Store in a cool and dry place
- 11 calories per drop

corn syrup, sucrose, caramel color, elderflower, honehound, hyssop, lemon balm, liden fiwer, malow, peppermint, sage, thyme, wild thyme, natural flavours



Questions or to report an adverse event call:

1617-848-4560

Monday to Friday: 9:00 am to 4:00 pm ET



# **Drug Facts**

Active ingredient (in each drop)

Purposes Cough Suppressant / Oral anesthetic

- Uses temporarily relieves;
  cough as may occur with a cold.
  cocasional minor initation 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, swelling, nausea, or vorniting, 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).

When using this product • do not exceed recommended dosage.

- Stop use and consult doctor if

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- sore mouth does not improve in 7 days.

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- Store in a cool and dry place.
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Inactive ingredients: Caramel color, blend of herbs extract (elderflower, horehound, hyssop, lemon balm, linden flowers, mallow, peppermint, sage, thyme, wild thyme), glucose syrup, natural flavors, sucrose

Questions? Or to report and adverse event call 1-617-848-4560. Monday - Friday, 9AM to 4PM EST.



## natural herbal cough drops

DIST. BY MEIJER DISTRIBUTION, INC. GRAND RAPIDS, MI 49544 www.meijer.com Questions or comments? 617-848-4560

MADE IN SPAIN

his product is not manufactured or distributed by Ricola Group AG, owner of the registered trademark Ricola®.



"Actual Size







PID 4713619



## NATURAL HERBAL COUGH DROPS

menthol pastille

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72628-107

ORAL Route of Administration

## Active Ingredient/Active Moiety

п	S v		
ı	Ingredient Name	Basis of Strength	Strength
ı	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A	A) MENTHOL	4.8 mg

## **Inactive Ingredients**

Ingredient Name	Strength		
LEMON BALM OIL (UNII: MJ76269K9S)			
PEPPERMINT (UNII: V95R5KMY2B)			
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)			
SAGE (UNII: 065C5D077J)			
THYME (UNII: CW6570BU4N)			
WILD THYME (UNII: KXK6180R8W)			
MALVA SYLVESTRIS LEAF (UNII: 17H39B00T5)			
HYSSOPUS OFFICINALIS FLOWERING TOP (UNII: X7HKN4FOJI)			
CARAMEL (UNII: T9D99G2B1R)			
HO REHO UND (UNII: K08036 XEJV)			
SUCROSE (UNII: C151H8M554)			
SAMBUCUS NIGRA FLO WER (UNII: 07V4DX094T)			
CORN SYRUP (UNII: 9G5L16BK6N)			

Product Characteristics				
Color	brown (dark)	Score	score with uneven pieces	
Shape	OVAL	Size	25mm	
Flavor	MENTHOL (and herbal)	Imprint Code	P	
Contains				

ı	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:72628-107-01	50 in 1 BAG; Type 0: Not a Combination Product	06/01/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	06/01/2020		

# Labeler - BOSTON NUTRACEUTICAL PRODUCTION, S.L (468121064)

# Registrant - Boston Nutraceutical Science SL (466061824)

Establishment					
Name	Address	ID/FEI	Business Operations		
BOSTON NUTRACEUTICAL PRODUCTION, S.L		468121064	manufacture(72628-107), label(72628-107)		

Revised: 6/2020 BOSTON NUTRACEUTICAL PRODUCTION, S.L