

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.

Natural Herbal Cough Drops

Menthol Cough Suppressant/ Oral Anesthetic

Active Ingredient in each drop Purposes

Menthol 4.8 mg
 Cough Suppressant
 Oral Anesthetic

Drug Facts	
Active ingredient (in each drop) Menthol 4.8 mg	Purposes Cough Suppressant/ Oral anesthetic
Uses temporarily relieves: <ul style="list-style-type: none"> ■ cough as may occur with a cold. ■ occasional minor irritation 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 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 <ul style="list-style-type: none"> ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema. ■ cough accompanied by excessive phlegm (mucus). 	
When using this product <ul style="list-style-type: none"> ■ do not exceed recommended dosage. 	
Stop use and consult doctor if <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. 	
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 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. May be repeated every two hours as necessary or as directed by a doctor.
children under 6 years:	ask a doctor.
Other information <ul style="list-style-type: none"> ■ Store in a cool and dry place. ■ 11 calories per drop. 	
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? 1-800-632-6900	

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 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 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

glucose 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:

1 800 632 6800

COMPARE TO the active ingredient of RICOLA*

*See back panel

RESEALABLE BAG

← Tear here

→ Tear here

Do not use if bag is torn or open

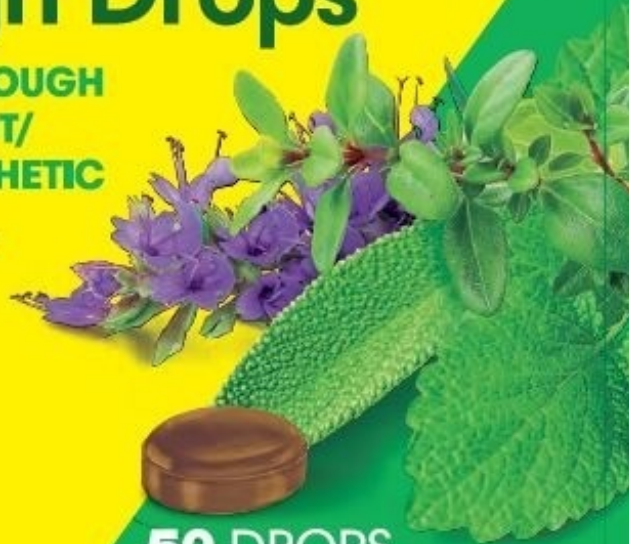


Herbal Cough Drops

**MENTHOL-COUGH SUPPRESSANT/
ORAL ANESTHETIC**

Soothes Sore Throat Pain

Temporarily Relieves Cough



50 DROPS

**Actual Size Depiction on Back

NATURAL HERBAL COUGH DROPS

menthol pastille

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72628-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.8 mg
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Inactive Ingredients

Ingredient Name	Strength
LEMON BALM OIL (UNII: MJ76269K9S)	
PEPPERMINT (UNII: V95R5KMY2B)	
HYSSOPUS OFFICINALIS FLOWERING TOP (UNII: X7HKN4FOJI)	
SAGE (UNII: 065C5D077J)	
THYME (UNII: CW6570BU4N)	
WILD THYME (UNII: KXK6I80R8W)	
TILIA CORDATA FLOWER (UNII: CFN6G1F6YK)	
CARAMEL (UNII: T9D99G2B1R)	
HOREHOUND (UNII: K08036XEJV)	
SUCROSE (UNII: C151H8M554)	
MALVA NEGLECTA WHOLE (UNII: S0QQA41760)	
CORN SYRUP (UNII: 9G5L16BK6N)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72628-111-01	50 in 1 BAG; Type 0: Not a Combination Product	05/12/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/12/2021	

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(72628-111) , label(72628-111)

Revised: 2/2023

BOSTON NUTRACEUTICAL PRODUCTION, S.L