HONEY LEMON 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.

Honey Lemon Cough Drops

Sugar Free 25 drops

Active Ingredient in each drop Purposes

Menthol 7.6 mg Cough Suppressant

Oral anesthetic

--- ◀ Tear here ---- 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



MENTHOL COUGH SUPPRESSANT Oral Anesthetic

Temporarily relieves cough & soothes sore throats.

Soothing Relief

Honey Lemon Flavor
*Actual Size Depiction on Back

25 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

Citric acid, eucalyptus oil, isomalt, stevia, flavor lemon oil, flavor honey extract, colorant turmeric, water

NPC FPO

FOT / EXP. DATE

 $^{\rm T}$ This product is not manufactured or distributed by the owner of the registered trademark Halls $^{\rm e}$

Distributed by:

Boston Nutraceutical Science LLC.

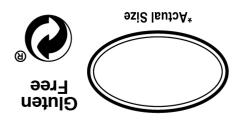
75 Arlington Street Suite 500.

Boston, MA 02116.

PRODUCT OF SPAIN.

Questions or Comments call

617-848-4560



tiavors, isomalt, stevia, turmeric (coloring). Inactive ingredients: Citric acid, eucalyptus oil, Excess consumption may cause laxative effect. May be useful for diabetics on the advise of a doctor. e cslories per drop. Other information 92K 9 GOCLOL Children under 5 years: a doctor. uecessary 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 of the reach of children. In case of accidental brofessional before use. Keep this and all drugs out It pregnant or breast-feeding, ask a health

- lasts or worsens.
 sore mouth does not improve in 7 days.
- corga peroirei en more unan racho, condes e recondition.
 dris accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
 sore throat is severe, or irritation, pain or redness
 - Stop use and consult doctor if cough persists for more than 7 days, tends to recur,
 - When using this product when not exceed recommended dosage.

condh accompanied by excessive phlegm (mucus).

Soothing Relief

מ פטטווופה פטוב ווווטמוה.

■ Ask a doctor before use if you have persistent or chronic cough such as occurs with

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.

- occasional minor irritation and sore throat.
- cough as may occur with a cold or inhaled irritants.

\text{Menthol V.V ang mersenent} \text{Ough auppressant} \text{V and but of the order} \text{Menthol Menthol V.V and but of the order} \text{Menthol Menthol Menthol V.V and but of the order} \text{Menthol Menthol V.V and but of the order} \text{Menthol Menthol Menthol V.V and but of the order} \text{Menthol Menthol Menthol Menthol V.V and but of the order \text{Menthol Menthol Me

Active ingredient (in each drop) Purposes

Drug Facts

Temporarily relieves cough

MENTHOL COUGH SUPPRESSANT Oral Anesthetic

Cough Drops

Sugar Free



	3. Press to reseal	2. Separate to open	Tear .	l	
. ear here 🕨 — —	 g รอิ	Resealable		Tear here	> — — -



Questions or comments call: 617-848-4560

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



SUGAR FREE Sweetened with Stevia Extract

Honey Lemon

Cough Drops

MENTHOL COUGH SUPPRESSANT Oral Anesthetic

Temporarily relieves cough & soothes sore throats.

Soothing Relief

Honey Lemon Flavor
*Actual Size Depiction on Back

25 DROPS

HONEY LEMON COUGH DROPS				
menthol pastille				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72628-101	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	7.6 mg	

Inactive Ingredients		
Ingredient Name	Strength	
EUCALYPTUS OIL (UNII: 2R04ONI662)		
LEMON OIL (UNII: 19 GRO 8 2 4 LL)		
HONEY (UNII: Y9H1V576FH)		
ISOMALT (UNII: S870P55O2W)		
WATER (UNII: 059QF0KO0R)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
STEVIA REBAUDIANA WHO LE (UNII: 6U422Y08O2)		
TURMERIC (UNII: 856 YO 1Z64F)		

Product Characteristics				
Color	yello w	Score	score with uneven pieces	
Shape	OVAL	Size	17mm	
Flavor	HONEY, LEMON	Imprint Code	None	
Contains				

Packaging			
# Item Code Package Description		Marketing Start Date	Marketing End Date
1 NDC:72628-101-01	25 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(72628-101), label(72628-101), pack(72628-101)

Revised: 9/2019 Boston Nutraceutical Production SL