

BENTASIL SUGAR FREE HONEY LEMON SOFT TEXTURE- menthol lozenge
CLOETTA ITALIA S.r.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.

Drug Facts

Active Ingredient

Menthol 5mg

Purpose

Cough Suppressant, Oral Anesthetic

Uses

- for the temporary relief of minor sore throat
- for the temporary relief of coughs due to a cold

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. 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 ask a doctor if

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.
- sore mouth does not improve in 7 days or irritation, pain or redness persists or worsens

Keep out of reach of children

Directions

- adults and children 5 years and over: slowly dissolve one drop in the mouth. May be repeated every 2 hours as needed.
- children under 5 years: ask a doctor

Other Information

- 3.1 calories per drop

Inactive Ingredients


- Ammonium glycyrrhizate, carnauba wax, coconut and or palm kernel oil, flavoring, gum arabic, maltitol, sorbitol

Product Label

57021217
resealable bag


Bentasil®

HONEY LEMON

Drug Facts	Drug Facts (continued)
Active ingredient (in each drop) Purpose Menthol 5 mg, Cough suppressant, Oral anesthetic	Directions • adults and children 5 years and over: slowly dissolve one drop in the mouth. May be repeated every 2 hours as needed. • children under 5 years: ask a doctor
Uses • for the temporary relief of minor sore throat • for the temporary relief of coughs due to a cold	Other information • 3.1 calories per drop
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. 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)	Inactive ingredients • Ammonium glycyrrhizate, carnauba wax, coconut and or palm kernel oil, flavoring, gum arabic, maltitol, sorbitol.
When using this product • do not exceed recommended dosage	 1 85531 00088 7
Stop use and ask a doctor if • cough persists more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition. • sore mouth does not improve in 7 days or irritation, pain, or redness persists or worsens	
Keep out of reach of children →	EXP. LOT #

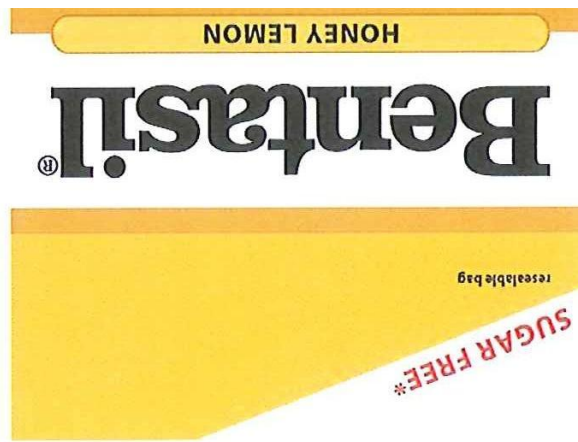
Product of Italy, Manufactured for:
Cloetta Italia S.R.L.
Via Milano 16-26100 Cremona (Italy)
www.bentasil.com

1.34 oz



SOFT
TEXTURE

20 THROAT LOZENGES



BENTASIL SUGAR FREE HONEY LEMON SOFT TEXTURE

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63104-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PALM KERNEL OIL (UNII: B0S90M0233)	
ACACIA (UNII: 5C5403N26O)	
MALTITOL (UNII: D65DG142WK)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	yellow (Amber)	Score	no score
Shape	ROUND (Lozenge)	Size	19mm
Flavor	HONEY (Honey and Lemon)	Imprint Code	NONE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63104-004-20	20 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2014	

Labeler - CLOETTA ITALIA S.r.l. (565049314)

Establishment

Name	Address	ID/FEI	Business Operations
CLOETTA ITALY SAN PIETRO IN CASALE PLANT		378806215	manufacture(63104-004)

Revised: 4/2014

CLOETTA ITALIA S.r.l.