

**BENTASIL SUGAR FREE EUCALYPTUS SOFT TEXTURE- menthol eucalyptus 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 5.8mg

Eucalyptus oil 5.7mg

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

- Phenylketonurics: Contains Phenylalanine (1.3) mg per drop. • 3.2 calories per drop

Inactive Ingredients

- aspartame (contains phenylalanine), carnauba wax, citric acid, coconut and or palm kernel oil, flavor, gum arabic, maltitol, sorbitol, xylitol

Product Label

57021221

resealable bag

Bentasil®

EUCALYPTUS

Drug Facts	Drug Facts (continued)
<p>Active ingredient (in each drop) Purpose Menthol 5.3 mg ————— Cough suppressant, Eucalyptus oil 5.7 mg ————— Oral anesthetic.</p> <p>Uses</p> <ul style="list-style-type: none"> • for the temporary relief of minor sore throat • for the temporary relief of coughs due to a cold <p>Warnings</p> <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. 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 ask a doctor if</p> <ul style="list-style-type: none"> • 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 <p>Keep out of reach of children →</p>	<p>Directions</p> <ul style="list-style-type: none"> • 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 <p>Other information</p> <ul style="list-style-type: none"> • Phenylketonurics: Contains Phenylalanine (1.3) mg per drop. • 3.2 calories per drop <p>Inactive Ingredients</p> <ul style="list-style-type: none"> • aspartame (contains phenylalanine), carnauba wax, citric acid, coconut and/or palm kernel oil, flavor, gum arabic, maltitol, sorbitol, xylitol.

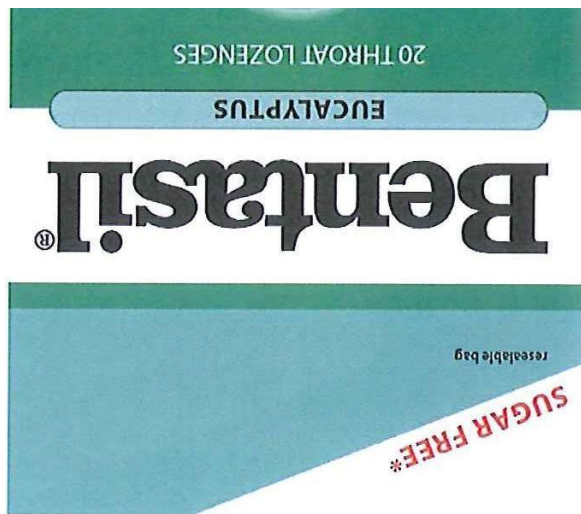
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EXP. LOT #

1.34 oz

SOFT
TEXTURE

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



BENTASIL SUGAR FREE EUCALYPTUS SOFT TEXTURE

menthol eucalyptus lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63104-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	5.8 mg
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	5.7 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
PALM KERNEL OIL (UNII: B0S90M0233)	
ACACIA (UNII: 5C5403N26O)	
MALTITOL (UNII: D65DG142WK)	
SORBITOL (UNII: 506T60A25R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	green (Aqua)	Score	no score
Shape	ROUND (Lozenge)	Size	19mm
Flavor	MENTHOL (Eucalyptus and Menthol)	Imprint Code	NONE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63104-003-20	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(63104-003)

Revised: 4/2014

CLOETTA ITALIA S.r.l.