

BENTASIL SUGAR FREE BLACKCURRANT 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

- Phenylketonurics: Contains Phenylalanine (0.9) mg per drop. • 3.7 calories per drop

Inactive Ingredients

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


Product Label

57021216
resealable bag

Bentasil®

BLACKCURRANT


<p>Drug Facts</p> <p>Active ingredient (in each drop) Purpose Menthol 5mg... Cough suppressant, 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>Drug Facts (continued)</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 (0.9) mg per drop. • 3.7 calories per drop <p>Inactive Ingredients Aspartame (contains phenylalanine), Beta Carotene, carnauba wax, citric acid, coconut and/or palm kernel oil, flavor, gum arabic, maltitol, sorbitol, xylitol</p>
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EXP. LOT#

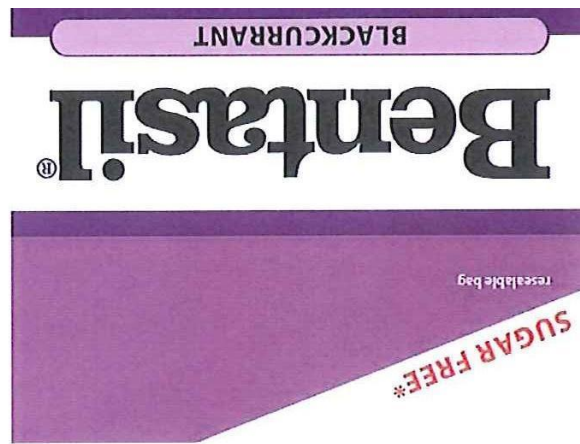
Product of Italy. Manufactured for:
Cioera Italia S.R.L.
Via Milano 16-26100 Cremona (Italy)
www.bentasil.com



1.34 oz

SOFT TEXTURE

20 THROAT LOZENGES



BENTASIL SUGAR FREE BLACKCURRANT SOFT TEXTURE

menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63104-001
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
ASPARTAME (UNII: Z0H242BBR1)	
BETA CAROTENE (UNII: 01YAE03M7J)	
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	purple (Dark Purple)	Score	no score
Shape	ROUND (Lozenge)	Size	19mm
Flavor	BERRY (Blackcurrant and Menthol)	Imprint Code	NONE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63104-001-20	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(63104-001)

Revised: 4/2014

CLOETTA ITALIA S.r.l.