CEPACOL EXTRA STRENGTH SORE THROAT HONEY LEMON- benzocaine and menthol lozenge ATLANTIC BIOLOGICALS CORP.

Cepacol ® Extra Strength* Sore Throat honey lemon

Drug Facts

Active ingredients (in each lozenge)	Purposes
Benzocaine 15 mg	Oral pain reliever
Menthol 2.6 mg	Oral pain reliever

Uses

Temporary relief of occasional

- sore throat
- sore mouth
- minor mouth irritation
- pain associated with canker sores

Warnings

METHEMOGLOBINEMIA WARNING

Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert

 Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or any other 'caine' anesthetics.

Sore throat warning

• If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Stop use and ask a doctor or dentist if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

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.

Do not exceed recommended dosage.

Directions

- adults and children 5 years of age and older: allow one lozenge to dissolve slowly in the mouth; may be repeated every 2 hours as needed or as directed by a doctor or dentist.
- children under 5 years of age: do not use

Other information

- store between 20-25°C (68-77°F)
- protect contents from humidity

Inactive ingredients

D&C yellow no. 10, FD&C yellow no. 6, flavors, isomalt, maltitol, propylene glycol, purified water, sodium bicarbonate, sucralose

Questions?

Call 1-866-682-4639

You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser Parsippany, NJ 07054-0224

Made in England

CEPACOL EXTRA STRENGTH SORE THROAT HONEY LEMON (BENZOCAINE AND MENTHOL) LOZENGE

17856-0732-01 CEPACOL EX-STR ORAL PAIN RELIVER (BENZOCAINE/MENTHOL) DELIVERS 15mg/2.6mg/1LOZ



See package insert for indications and dosage schedule

Honey Lemon Flavored Oral Pain Reliever. Each Lozenge contains 15mg of Benzocaine and 2.6mg of Menthol. Protect content from humidity. Store at 20°-25°C (68°-77°F). **Keep this and all Medications out of the reach of children**



17856-0732-01 Dosage 15mg/2.6mg/1LOZ

CEPACOL EX-STR ORAL
PAIN RELIVER

Qty: 50 LOZENGES

GTIN: 00317856073219

Exp: 11/13/24

Lot: XXXXXXXXXXX

OTC

Packaged by:Unit Dose Solutions Morrisville, NC 27560 Distributed by: Atlantic Biologicals Corp. Miami, FL 33179

Rev.08/21

Call to Reorder:

CEPACOL EXTRA STRENGTH SORE THROAT HONEY LEMON

benzocaine and menthol lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0732(NDC:63824-732)
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 mg	

Inactive Ingredients		
Ingredient Name	Strength	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ISOMALT (UNII: S870P55O2W)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	18mm
Flavor	HONEY (Honey-Lemon)	Imprint Code	S
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:17856- 0732-1	50 in 1 BOX	04/17/2024		
1	NDC:17856- 0732-2	1 in 1 POUCH; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	07/15/2013	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Registrant - ATLANTIC BIOLOGICALS CORP. (047437707)

Revised: 6/2025 ATLANTIC BIOLOGICALS CORP.