

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

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**Cēpacol®**  
**Extra Strength\* Sore Throat honey lemon**

***Drug Facts***

<b><i>Active ingredients (in each lozenge)</i></b>	<b><i>Purposes</i></b>
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 EXTRA**  
**STRENGTH**  
**(BENZOCAINE/MENTHOL) 15**  
**MG/2.6 MG LOZENGES**



See package insert for indications and dosage schedule

Store at 20°-25° C (68°-77° F) Protect contents from humidity.  
 \*\*\*\* Keep this and all Medication out of the reach of children



17856-0732-01

Dosage: 15 mg/2.6 mg

CEPACOL

Qty: 50 Lozenges



GTIN: 00117856073215

S/N: 01284901

Exp: 07/28/21

Lot: 012849

**OTC**

Packaged by: Unit Dose Solutions  
 Morrisville, NC 27560

Distributed by: AtlanticBiologics Corp,  
 Miami FL 33179

Rev.09/19

**Call to Reorder: 800.509.7592**

**CEPACOL EXTRA STRENGTH SORE THROAT HONEY LEMON**

benzocaine and menthol lozenge

**Product Information**

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

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C Yellow No. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C Yellow No. 6</b> (UNII: H77VEI93A8)	
<b>isomalt</b> (UNII: S870P55O2W)	
<b>maltitol</b> (UNII: D65DG142WK)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>sodium bicarbonate</b> (UNII: 8MDF5V39QO)	
<b>sucralose</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	18mm
<b>Flavor</b>	HONEY (Honey-Lemon)	<b>Imprint Code</b>	S
<b>Contains</b>			

### 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)

### Establishment

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	REPACK(17856-0732)