

**SORE THROAT LOGENZES SORE THROAT- benzocaine and menthol lozenge
ATLANTIC BIOLOGICALS CORP.**

Cēpacol

SORE THROAT

Drug Facts

<i>Active ingredients (in each lozenge)</i>	<i>Purpose</i>
Benzocaine 15 mg	Oral pain reliever
Menthol 3.6 mg	Oral pain reliever

Uses

temporary relief of occasional

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

Warnings

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.

Do not use in a child under 5 years of age.

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 or older: allow 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: ask a doctor

Other information

- tamper evident packaging: Do not use if outer box or blister is open or damaged.
- store at room temperature
- protect contents from moisture

Inactive ingredients

Glucose syrup, N&A flavoring, propylene glycol, red #40, sucrose, and water. Soybean oil used as processing aid.

Questions?

Call 1-800-616-2471

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

PRINCIPAL PANEL

17856-6255-01
SORE THROAT LOZENGE
(BENZOCAINE/MENTHOL)
DELIVERS 15-3.6mg/1LOZ



See package insert for indications and dosage schedule

Cherry flavored oral anesthetic for fast, long lasting relief of occasional minor irritation, pain, sore mouth and sore throat. Store at room temperature and protect from moisture.
****Keep this and all Medication out of the reach of children****



17856-6255-01 Dosage **15-3.6mg/1LOZ**
SORE THROAT LOZENGES Qty: **50 LOZENGES**



GTIN: 00117856625513
 S/N: XXXXXXXXXXXX
 Exp: 07/24/24
 Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
 Miami, FL 33179

Rev.08/21

Call to Reorder:

SORE THROAT LOZENGES SORE THROAT

benzocaine and menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-6255(NDC:0904-6255)
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	3.6 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CORN SYRUP (UNII: 9G5L16BK6N)	
ALLYL SUCROSE (UNII: VI3D59RW0U)	
HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	18mm
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-6255-1	50 in 1 BOX, UNIT-DOSE	07/26/2024	
1	NDC:17856-6255-2	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	M013	12/28/2012	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTION		360804194	repack(17856-6255)

Revised: 7/2024

ATLANTIC BIOLOGICALS CORP.