

**ORASEP- benzocaine, menthol, cetylpyridinium chloride liquid**  
**Llorens Pharmaceutical International Division**

*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.*

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**Active Ingredients :**

Benzocaine..... 2% Anesthetic

Menthol.....0.5% Anesthetic

Cetylpyridinium Chloride.....0.1% Antiseptic

**Purpose**

**Oral anesthetic**

**Oral antiseptic**

**Uses for temporary relief of:**

- Occasional minor sore throat pain and dry scratch throat.
- Pain due to canker sores. Pain due to minor irritation or injury of the mouth and gums. Pain due to minor dental procedures, minor irritations cause by dentures or orthodontic appliances.

**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 sever, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomitings, consult a doctor promptly.

**Stop use and ask a doctor if** sore mouth symptoms do not improve in 7 days, or if irritation, pain or redness persist or worsens.

**Do not exceed recommended dosage.**

**When using this product** do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor.

**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.

**If pregnant or breast feeding,** ask a health professional before use.

**Directions:**

- Adults and children 6 years of age or older: Using a q-tip apply the solution to the affected area. Use up to 4 times daily or as directed by a doctor or dentist.
- Children under 6 years of age: ask a doctor or dentist.

**Inactive Ingredients:** Artificial and natural flavors, methylparaben, polyoxyl hydrogenated castor oil, propylene glycol, propylparaben, purified water, and sucralose.

**Questions or comments? 1-866-595-5598**

**Drug Facts**

Active Ingredients in each 1mL	Purpose
Benzocaine 2%	Oral Anesthetic
Cetylpyridinium chloride 0.1%	Oral Antiseptic
Menthol 0.5%	Oral Anesthetic

**Uses for temporary relief of:**

- Occasional minor sore throat pain and dry scratchy throat.
- Pain due to canker sores. Pain due to minor irritation or injury of the mouth and gums. Pain due to minor dental procedures, minor irritations caused by dentures or orthodontic appliances.

**Warnings:**

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If pregnant or breast feeding, ask a health professional before use. Keep this and all drugs out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not exceed recommended dosage.

When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water. If irritation persists, consult a doctor.

NDC 54859-503-01

**ORASEP****SOLUTION**

- ANTISEPTIC
- ANESTHETIC

Lemon-Honey Flavor

1 FL. OZ. (30 ML)

**Drug Facts (continued)****Directions:**

- Adults and children 6 years of age or older: Using a q-tip apply the solution to the affected area. Use up to 4 times daily or as directed by a doctor or dentist.
- Children under 6 years of age: ask a doctor or dentist.

**Other Information:**

- Store at room temperature 15°-30°C (59°-86°F). Tamper Evident Feature: Do not use if seal around the nozzle is missing or disturbed.

**Inactive Ingredients:** Artificial and natural flavors, methylparaben, polyoxyl hydrogenated castor oil, propylene glycol, propylparaben, purified water, and sucralose.

**Questions or Comments?** 1-866-595-5598

Code #: L-88

Manufactured by:

**LLORENS**  
PHARMACEUTICAL  
International Division, Inc.  
www.llorenspharm.com

Lot:

Exp:

Rev 01/18



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**ORASEP**

benzocaine, menthol, cetylpyridinium chloride liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54859-503
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	2 mg in 100 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 mg in 100 mL
<b>CETYL PYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P) (CETYL PYRIDINIUM - UNII:CUB7J10JV3)	CETYL PYRIDINIUM CHLORIDE	0.1 mg in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-503-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2010	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/01/2010	

**Labeler** - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2020

Llorens Pharmaceutical International Division