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.

Active Ingredients:

Benzocaine..... 2% Anesthetic

Cetylpyridinium Chloride.....0.1% Antiseptic

Menthol.....0.5% Anesthetic

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 than2 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: spray into throat or onto affected area with one spray per use. 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

ORASEP

benzocaine, menthol, cetylpyridinium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54859-504
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	2 mg in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.5 mg in 100 mL
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-504-01	30 mL in 1 BOTTLE, SPRAY; 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)

Registrant - Llorens Pharmaceutical International Division (037342305)

Establishment

Name	Address	ID/FEI	Business Operations
Lex Inc.		046172888	manufacture(54859-504)

Revised: 12/2020 Llorens Pharmaceutical International Division