ACTISEP- benzocaine, menthol, cetylpyridinium chloride solution
Actipharma, Inc

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.

ACTISEP® SOLUTION

Drug Facts

Active ingredients

Benzocaine 2%
Menthol 0.5%
Cetylpyridinium Chloride 0.1%

Purposes

Oral Anesthetic

Oral Anesthetic

Oral Antiseptic

Uses:

• For temporary relief of occasional minor sore throat pain and dry, scratchy throat.
• For the temporary relief of pain associated with canker sores, minor irritation or injury of the mouth and gums, minor dental procedures, minor irritations caused by dentures or orthodontic appliances.

Warnings:

Methemoglobinemia warning:

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. 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 other “caine” anesthetics. If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsens, see your dentist or doctor promptly.

Do not exceed recommended dosage.

Do not use

- in or near eyes
- for teething
- in children under 2 years of age

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

In the event of accidental contact with eyes, flush immediately with water and continuously for 10 minutes. Seek immediate medical attention if pain persists.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions:

adults and children 2 years of age or older:	Spray Actisep several times to affected area in mouth or lips. Do not use more than 4 times a day.
children between 2 and 12 years of age:	should be supervised in the use of this product.
children under 2 years of age:	do not use

As a gargle or mouthwash, Adults and Children 12 years and over, place ½ teaspoon (2.5 mL) in ½ glass of warm
water several times a day. Do not use more than 4 times a day.

Inactive ingredients:

Castor oil, methylparaben, propylparaben, propylene glycol, purified water, sucralose.

Other information:

Tamper Evident Feature: Do not use if heat seal under cap is torn, broken or missing. Store at controlled room temperature 15-30°C (59-86°F).

Questions or comments?

(787) 608-0882

Contains the same active ingredients as Orasep® Solution*

ANTISEPTIC • ANESTHETIC

Alcohol Free

Manufactured in the USA for

ActiPharma, Inc.
Dorado, PR 00646

*Orasep® Solution is a registered trademark of Llorens Pharmaceutical Corp.
This product is not manufactured, distributed or marketed by Llorens Pharmaceutical Corp.

Packaging

NDC 63102-106-01

ACTISEP®

SOLUTION

Contains the same active ingredients as Orasep® Solution*

ANTISEPTIC • ANESTHETIC

Alcohol Free

ActiPharma
Cost-Effective Solutions

1 fl. oz. (30 mL)

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Lift Here for *Drug Facts*

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Drug Facts

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Cetylpyridinium Chloride	0.1%	Oral Antiseptic

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Drug Facts (continued)

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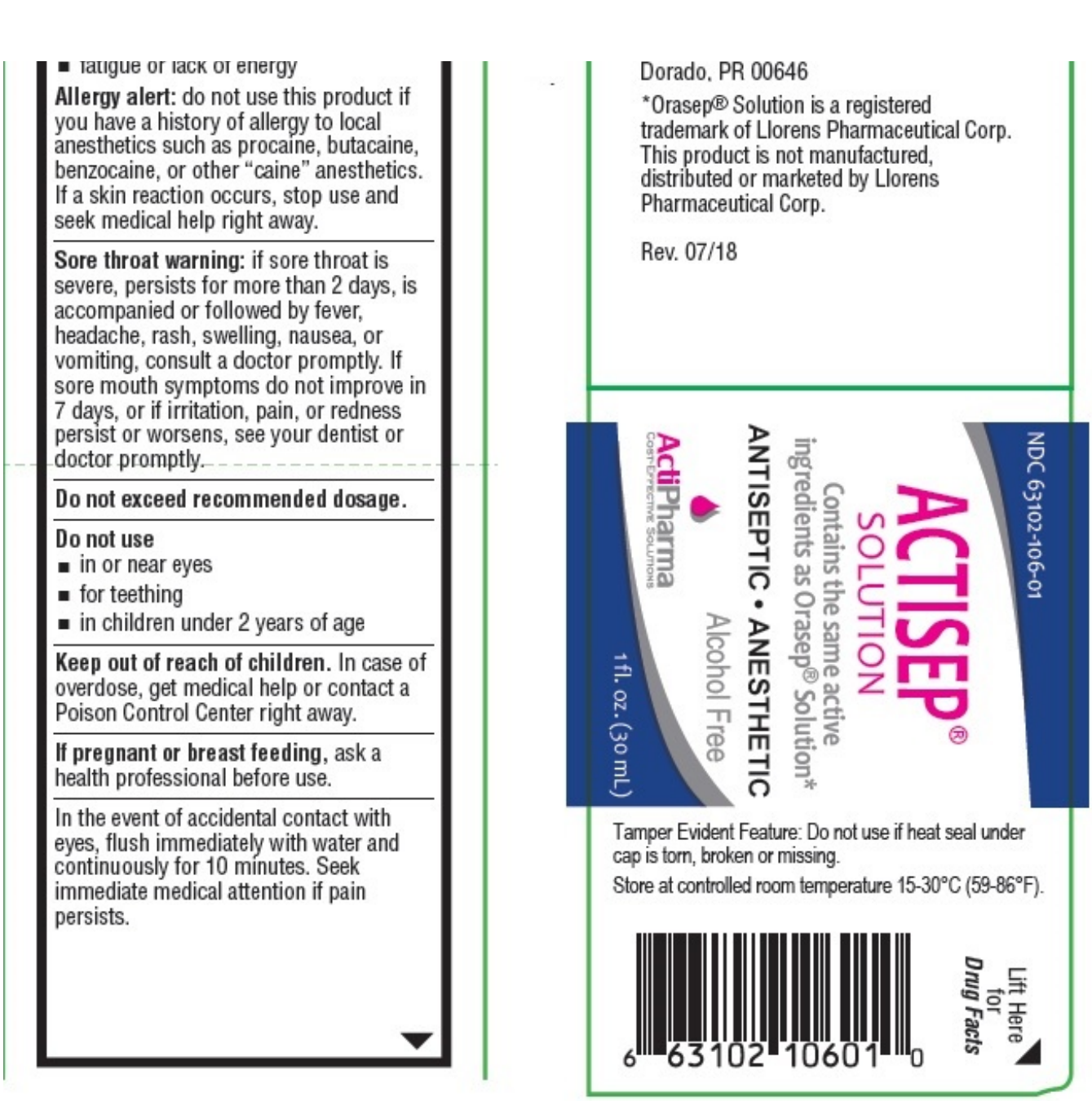
Manufactured in the USA for
ActiPharma, Inc.



ACTISEP

benzocaine, menthol, cetylpyridinium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63102-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	2 g in 100 mL
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED	0.5 g

MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	FORM	in 100 mL
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P) (CETYLPYRIDINIUM - UNII:CUB7JI0JV3)	CETYLPYRIDINIUM CHLORIDE	0.1 g in 100 mL

Inactive Ingredients

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

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MENTHOL	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63102-106-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/28/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/28/2015	

Labeler - Actipharma, Inc (079340948)

Revised: 12/2018 Actipharma, Inc