

ACTISEP- benzocaine, menthol, cetylpyridinium chloride spray

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® SPRAY

Drug Facts

Active ingredients

Benzocaine2%
Menthol0.5%
Cetylpyridinium Chloride0.1%

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 Do not exceed recommended dosage.

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 Actisept 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® Spray*

ANTISEPTIC • ANESTHETIC

Alcohol Free

Manufactured in the USA for ActiPharma, Inc.

Dorado, PR 00646

*Orasep® Spray is a registered trademark of Llorens Pharmaceutical Corp.

This product is not manufactured, distributed or marketed by Llorens Pharmaceutical Corp.

Packaging



NDC 63102-107-01

ACTISEP[®] SPRAY

Contains the same active ingredients as Orasep[®] Spray*
ANTISEPTIC • ANESTHETIC



Alcohol Free

1 fl. oz. (30 mL)

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).



Drug Facts

Active ingredients	Purposes
Benzocaine 2%	Oral Anesthetic
Menthol 0.5%	Oral Anesthetic
Cetylpyridinium Chloride 0.1%	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

Drug Facts (continued)

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.

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).

Inactive ingredients:

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

Questions or comments?

(787) 608-0882

Manufactured in the USA for ActiPharma, Inc. Dorado, PR 00646

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

Rev. 07/18

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

Keep out of 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.

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



ACTISEP

benzocaine, menthol, cetylpyridinium chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63102-107
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 FORM	0.5 g 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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
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:63102-107-01	30 mL in 1 BOTTLE, SPRAY; 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