

GILTUSS BUCALSEP- benzocaine, menthol, zinc chloride spray
Dextrum Laboratories Inc.

Giltuss Bucalsep

Active Ingredients

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Benzocaine, 6.5% ----- Anesthetic

Menthol, 0.1% ----- Anesthetic

Zinc Chloride 0.12% ----- Astringent

Drug Facts

Active ingredients

Purposes

Benzocaine, 6.5%	Anesthetic
Menthol, 0.1%	Anesthetic
Zinc chloride 0.12%	Astringent

Uses

temporarily relieves pain due to the following mouth and gum irritations:

- sore mouth and throat
- canker sores
- minor dental procedures
- dentures or orthodontic appliance

Warnings

Do not use

- **IN OR NEAR THE EYES.** In the event of accidental contact with the eyes, flush immediately and continuously for 10 minutes. Seek immediate medical attention if pain or irritation persists
- this product for more than 7 days unless directed by a doctor or a dentist

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Drug Facts (continued)

Methemoglobinemia Warning: use of this product may cause methemoglobinemia, a rare but 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" anesthetic

Do not use

- for teething
- in children under 2 years of age
- for more than 7 days unless directed by a dentist or doctor

When using this product

- do not exceed recommended dosage
- avoid contact with eyes. In case of eye contact, rinse with water

Stop use and ask a doctor if

- sore throat is severe, persists for more than 2 days, is accompanied, or followed by fever, headache, rash, nausea or vomiting

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If pregnant or breastfeeding, ask a health professional before use.

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 and older

- apply to affected area
 - gargle, swish around in the mouth, or allow to remain in place at least 1 minute and then spit out
 - use up to 4 times daily or as directed by a dentist or doctor
 - children under 12 years of age should be supervised in the use of the product
- Children under 2 years of age: do not use**

Other information

Store at room temperature

Inactive ingredients

Cetylpyridinium Chloride, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Spearmint Flavor and Sucralose.

Questions or Comments?

Call **1-787-848-9114**, Mon.-Fri. 9:00 a.m. thru 5:00 p.m. EST. Call your doctor for medical advice in the event of side effects.

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NDC: 58552-135-01

ALCOHOL FREE
SIN ALCOHOL

G

NEW PUMP

Oral Spray

Giltuss
BUCALSEP

SORE THROAT, ORAL ANESTHETIC AND ORAL ASTRINGENT

DOLOR DE GARGANTA, ANESTESICO Y ASTRINGENTE ORAL

1 FLOZ (30 mL)

SPLENDENT FLAVOR, SABA I MENTA

ALCOHOL FREE. SUGAR FREE. DYE FREE.
SIN ALCOHOL, SIN AZÚCAR, SIN COLORANTES.

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Oral Spray

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Alcohol free

Oral Spray

Giltuss Bucalsep

Sore, Throat, Oral astringent

1 fl oz (30 mL)

Alcohol free, sugar free, dye free

Spearmint flavor

GILTUSS BUCALSEP

benzocaine, menthol, zinc chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65852-015
Route of Administration	ORAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC CATION (UNII: 13S1S8SF37) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.12 mg in 100 mL
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6.5 mg in 100 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65852-015-01	1 in 1 CARTON	07/26/2018	
1		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	07/26/2018	

Labeler - Dextrum Laboratories Inc. (007392322)

Revised: 9/2025

Dextrum Laboratories Inc.