

GILTUSS BUCALSEP- benzocaine, menthol, zinc chloride spray
Gil Pharmaceutical Corp

Giltuss Bucalsep

Drug Facts

Active ingredients (in each 30 mL)

Benzocaine, 6.5% (1950 mg)

Zinc Chloride, 0.12% (36 mg)

Menthol, 0.1% (30 mg)

Purposes

Anesthetic

Astringent

Anesthetic

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

Ask a doctor or pharmacist before use if you have

- a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics

When using this product, do not exceed recommended dosage

Stop use and ask a doctor or dentist if

- sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, swelling, rash, nausea, or vomiting
- symptoms do not improve in 7 days
- irritation, pain or redness persists or increases, or a rash appears on the skin

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

Keep out of reach of children.In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Directions

Adults and children 2 years of age and older:

- Spray Giltuss Bucalsep several times to affected areas in the mouth or lips or as directed by a doctor or dentist
- use as a gargle or mouthwash
- 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 doctor or dentist
- **Children under 12 years of age:** should be supervised in the use of this product

Children under 2 years of age: consult a dentist or doctor

Other information

- **Tamper evident:** Do not use if safety seal is broken or missing
- Store at room temperature

Questions or Comments?

Call **1-800-848-9114**, Mon. - Fri. 9:00 a.m. thru 5:00 p.m. EST. Call your doctor for medical advice in the event of side effects.

Inactive ingredients: Cetylpyridinium chloride, Spearmint Flavor, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Sucralose

MANUFACTURED FOR:

GIL PHARMACEUTICAL CORP.

PONCE, PUERTO RICO 00717-1565

giltuss.com

Uses

- for the temporary relief of occasional minor irritations, pain, sore mouth, sore throat, pain associated with canker sores, pain due to minor irritation or injury of the mouth and gums, pain due to dental procedures, pain due to minor irritations caused by dentures or orthodontic appliances, sore gums

MAXIMUM STRENGTH

Oral Spray

Giltuss BUCALSEP®

SORE THROAT AND ORAL INFECTIONS

ALCOHOL FREE. SUGAR FREE. DYE FREE

RELIEVES

- SORE THROAT
- THROAT INFECTION
- CANKER SORES
- OTHER ORAL PAINS AND INJURIES

SPEARMINT FLAVOR

1FL OZ (30 mL)

Inactive Ingredients

Ingredient Name	Strength
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SPEARMINT (UNII: J7I2T6IV1N)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	yellow (Light yellow)	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-135-01	1 in 1 CARTON	07/26/2018	
1		30 mL in 1 BOTTLE, SPRAY; 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 - Gil Pharmaceutical Corp (176826592)

Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58552-135)

Revised: 10/2023

Gil Pharmaceutical Corp