

G-BUCAL-C- menthol, unspecified form and zinc chloride spray
MCLAREN MEDICAL 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.

G-BUCAL-C

DRUG FACTS

Active Ingredients (in each 30 mL)	Purpose
Menthol 0.15%	Anesthetic/Analgesic
Zinc Chloride 0.1%	Astringent

INDICATIONS

For the temporary relief of occasional minor throat irritation, 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 minor dental procedures, pain due to minor irritations caused by dentures or orthodontic appliance, sore gums due to teething in infants and children 4 months of age and older.

DIRECTION FOR SPRAY

Spray G-Bucal-C several times as directed by physician or dentist to affected are in the mouth or lips. Children under 12 years of age should be supervised in the use of this product. Children under two years of age consult a doctor or dentist. As a gargle or mouthwash, ½ teaspoon in a half glass of warm water. Gargle swish around 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.

INACTIVE INGREDIENTS

Benzocaine, cetylpyridinium chloride, citric acid, glycerin, peppermint oil, polyethylene glycol, purified water, sodium citrate and sodium saccharin.

Each 30mL Contains:

Cetylpyridinium Chloride	30 mg
Benzocaine	600 mg
Menthol	45 mg
Zinc Chloride	30 mg

WARNINGS

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. Do not use this product for more than 7 days unless directed by a dentist or doctor. If irritation, pain or redness persists or worsens, or if swelling, rash or fever develops, see your dentist or doctor promptly. **DO NOT EXCEED RECOMMENDED DOSAGE.** Do not use this product if you have history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics. Discontinue use and consult a doctor if irritation persists or increases or a rash appears on the skin. Fever and nasal congestion are not symptoms of teething and may

indicate the presence of infection. If these symptoms persist, consult your doctor. **DO NOT USE IN OR NEAR THE EYES.** In the event of accidental contact with eyes, flush immediately and continuously for ten minutes. See immediate medical attention if pain or irritation persists.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Label

NDC-43913-402-30

**G-Bucal-C
Oral Solution Spray**

Anesthetic • Astringent
Alcohol Free • Peppermint Flavor

1 FL OZ (30 mL)

For Dispensing Under
Pharmaceutical Supervision Only

McLaren Medical

<p>Each 30mL Contains:</p> <p>Cetylpyridinium Chloride 30 mg Benzocaine 600 mg Menthol 45 mg Zinc Chloride 30 mg</p> <p>WARNINGS: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, see your dentist or doctor promptly. Do not use this product for more than 7 days unless directed by a dentist or doctor. If irritation, pain or redness persists or worsens, or if swelling, rash or fever develops, see your dentist or doctor promptly. DO NOT EXCEED RECOMMENDED DOSAGE. Do not use this product if you have history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics. Discontinue use and consult a doctor if irritation persists or increases or a rash appears on the skin. Fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your doctor. DO NOT USE IN OR NEAR THE EYES. In the event of accidental contact with eyes, flush immediately and continuously for ten minutes. See immediate medical attention if pain or irritation persists. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. DO NOT ACCEPT IF SEAL IS BROKEN OR MISSING. Lot#: [] EXP. DATE: []</p>	<p>NDC-43913-402-30</p> <p>G-Bucal-C Oral Solution Spray</p> <p>Anesthetic • Astringent Alcohol Free • Peppermint Flavor</p> <p>1 FL OZ (30 mL)</p> <p>For Dispensing Under Pharmaceutical Supervision Only</p> <p></p>	<p>DRUG FACTS: Active Ingredients (in each 30 mL) Purpose Menthol 0.15% Anesthetic/Analgesic Zinc Chloride 0.1% Astringent</p> <p>INDICATIONS: For the temporary relief of occasional minor throat irritation, 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 minor dental procedures, pain due to minor irritations caused by dentures or orthodontic appliance, sore gums due to teething in infants and children 4 months of age and older.</p> <p>DIRECTION FOR SPRAY: Spray G-Bucal-C several times as directed by physician or dentist to affected are in the mouth or lips. Children under 12 years of age should be supervised in the use of this product. Children under two years of age consult a doctor or dentist. As a gargle or mouthwash, ½ teaspoon in a half glass of warm water. Gargle swish around 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.</p> <p>INACTIVE INGREDIENTS: Benzocaine, cetylpyridinium chloride, citric acid, glycerin, peppermint oil, polyethylene glycol, purified water, sodium citrate and sodium saccharin. Manufactured in the USA for: McLaren Medical Inc, 1602 Alton Rd# 513, Miami Beach, FL 33139</p> <p style="text-align: center;">  N 3 4391-3402-30 2 </p>
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

G-BUCAL-C

menthol, unspecified form and zinc chloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:439 13-402
Route of Administration	OROPHARYNGEAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	45 mg in 30 mL
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	30 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
BENZOCAINE (UNII: U3RSY48JW5)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43913-402-30	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 NOT FINAL	part356	01/01/2012	

Labeler - MCLAREN MEDICAL INC (013770591)