GUMSOL - benzocaine, zinc chloride spray
Kramer Novis

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.

GUMSOL

Drug Facts

Active ingredients (in 30 mL)

Benzocaine (5%)

Zinc Chloride (0.1%)

Purposes

Anesthetic

Astringent

Use

Temporarily relieves pain due to toothaches, canker sores or minor mouth injuries of the mouth and gums 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" anesthetic. If 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

Do not use*(unless directed by a doctor):* • more than directed • for more than 7 days • in children under 2 years of age • for teething.

Stop use and see a doctor promptly if: • sore mouth symptoms do not improve in 7 days

• *irritation, pain or redness persist or worsen*

• *swelling, rash or fever develops.*

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

KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison

Control Center right away.

Directions

Adults and children 12 years of age and older	Dry affected area with absorbent cotton. Spray 4 times daily or as directed by physician.
Children under 12 years of age	Should be supervised in the usage of this product.
Children under 2 years of age	**Do not use.**

Other information:

• **Phenylketonurics:** Contains phenylalanine 2.5mg/mL.

• Store at controlled room temperature: 15°C-30°C (59°F-86°F)

• Tamper Evident: Do not use if imprinted foil seal over bottle opening is torn, broken, or missing.

Inactive ingredients

Aspartame, cetylpyridinium chloride, glycerin, menthol, methylparaben, peppermint flavor, propylene glycol, propylparaben, and water (purified).

Questions or comments?

Kramer Novis San Juan, PR 00917. Monday to Friday

(8am-4pm). 787-767-2072 www.kramernovis.com

Spray

Alcohol Free

Manufactured in the USA for

Kramer Novis, San Juan, PR 00917

Packaging

NDC 52083-714-01

Spray GUMSOL®

Anesthetic • Astringent
Alcohol Free

Net Contents:1 fl.oz. (30mL)

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Rev. 07/18

Manufactured in the USA for
Kramer Novis, San Juan, PR 00917

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Lift here for more information

Drug Facts *(continued)*

Stop use and see a doctor promptly if: • *sore mouth symptoms do not improve in 7 days*
• *irritation, pain or redness persist or worsen*
• *swelling, rash or fever develops.*

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GUMSOL

benzocaine, zinc chloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-714
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	1.5 g in 30 mL
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.03 g in 30 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ASPARTAME (UNII: Z0H242BBR1)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52083-714-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2014	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC monograph not final	part356	02/28/2014	

Labeler - Kramer Novis (090158395)

Revised: 11/2018 Kramer Novis