

ANESGERM- benzocaine gel
World Perfumes, 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.

Active Ingredient	Purpose
Benzocaine 20%	Pain Reliever

Uses

for the temporary relief of pain due to:

- toothache
- minor irritation or injury of the mouth and gums
- infection cause by dentures or orthodontic appliances
- sore gums due to teething in infants and children 4 months of age and older

Keep out of reach of children. In case of overdose, get medical help immediately.

Directions

children under 12 years of age should be supervised in the use of this product. Adults and children 12 years of age and older:

- apply to the affected area up to 4 times a day or as directed by a dentist or doctor

Children under 2 years of age:

- consult a dentist or doctor

Teething Infants 4 months of age and over:

- apply to the affected area up to 4 times daily or as directed by a dentist or doctor

Infants under 4 months of age:

- consult a dentist or doctor

GERMA

Anesterm

Maximum Strength Oral Pain Reliever

20% Benzocaine PLUS Oil of Cloves

Fast Pain Relief

Easy To Apply

- Toothache
- Sore Gums
- Teething
- Denture Irritation
- Braces Irritation

Warnings

Do not exceed recommended dosage.

Do not use

- for more than 7 days unless directed by a dentist or doctor

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

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- infection, pain, or redness persists or worsens
- swelling, rash or fever develops
- fever & nasal congestion are present in teething infants 4 months of age and over

These symptoms may be a sign of infection or a serious condition.

Inactive Ingredients

polyethylene glycol-75, polyethylene glycol-8, glycerin, propyl paraben, methyl paraben, sodium saccharin, clove oil

GERMA Maximum Strength Oral Pain Reliever
AMESGERM™
 20% BENZOCANE PLUS OIL OF CLOVES

Fast Pain Reliever
 Easy to Apply

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- Denture Irritation
- Braces Irritation

0.5 FL. OZ. (14.8mL)

Drug Facts

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Uses ■ for the temporary relief of pain due to: ■ toothache ■ minor irritation or injury of the mouth & gums ■ irritation caused by dentures or orthodontic appliances ■ sore gums due to teething in infants and children 4 months of age and older.

Warnings ■ Do not exceed recommended dosage. Keep out of reach of children. In case of overdose, get medical help immediately.

Do not use ■ for more than 7 days unless directed by a dentist or doctor ■ if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics.

Stop use and ask a dentist or doctor if ■ sore mouth symptoms do not improve in 7 days ■ irritation, pain or redness persists or worsens ■ swelling, rash or fever develops ■ fever & nasal congestion are present in teething infants 4 months of age and over. **These symptoms may be a sign of infection or a serious condition.**

Directions ■ children under 12 years of age should be supervised in the use of this product. Adults and children 2 years of age and older ■ apply to the affected area up to 4 times daily or as directed by a dentist or doctor. Children under 2 years of age ■ consult a dentist or doctor. Teething infants 4 months of age and over: ■ apply to the affected area up to 4 times daily or as directed by a dentist or doctor. Infants under 4 months of age ■ consult a dentist or doctor.

Other information ■ store between 15° to 30°C (59° to 86°F).

Inactive Ingredients ■ Polyethylene Glycol-75, Polyethylene Glycol-8, Glycerin, Propyl Paraben, Methyl Paraben, Sodium Saccharin, Clove Oil.

Distributed by:
Germa Products, Inc.
 Miami, Florida 33186
 www.germa.net

ANESGERM

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10095-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CLOVE OIL (UNII: 578389D6D0)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7H9T)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10095-001-01	0.5 g in 1 PACKAGE; 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	04/30/2015	

Labeler - World Perfumes, Inc (101312044)

Establishment

Name	Address	ID/FEI	Business Operations
World Perfumes, Inc		101312044	manufacture(10095-001)