

**ANESGERM LA MUELA FAST PAIN RELIEF- benzocaine 20% liquid**  
**Germa Products, LLC**

*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.*

-----  
**Anesgerm (La Muella)**

**Active Ingredient**

Benzocaine 20%

**Do Not Use if**

Do not use ■ for more than 7 days unless directed by a dentist or doctor ■ for teething. ■ in children under 2 years of age.

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” anesthetics. If a skin reaction occurs, stop use and seek medical help right away.

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

**Directions**

Adults & children, 12 yrs of age & older ■ Apply to the affected area up to 4 times daily or as directed by a dentist or doctor.

Children 2 yrs of age & older ■ As directed by a dentist or doctor.

Children under 2 years of age ■ Do not use.

**Purpose**

Pain Reliever

**Warnings**

Warnings:

Do not exceed recommended dosage

Keep out of reach of children

In case of overdose, get medical help immediately.

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.

Do not use:

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

for teething in children under 2 years of age.

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” anesthetics. If a skin reaction occurs, stop use and seek medical help right away.

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.

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

## Other Information

Store between 15° to 30°C (59° to 86°F).

## Inactive Ingredients

Clove Oil, Ethyl Alcohol, Glycerin, Polyethylene Glycol, Propylene Glycol, Sodium Saccharin, Sodium Methylparaben.

## Uses

Uses ■ for the temporary relief of pain due to. ■ toothache ■ minor irritation or injury of the mouth & gums ■ irritation cause by dentures or orthodontic appliances ■ sore gums.

## Warning

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

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.



Easy to Apply

Net Wt.: 0.5 FL. OZ.  
(14.8mL.)



Questions or Comments:  
1-305-278-0033, M-F, 9-5 Eastern  
[www.germa.net](http://www.germa.net)

Referred to box for "Drug Facts"  
or go to [www.germa.net](http://www.germa.net)

Keep the bottle  
tightly closed



### Drug Facts

Active ingredient	Purpose
Benzocaine 20%	Pain Reliever

**Uses** ■ for the temporary relief of pain due to. ■ toothache ■ minor irritation or injury of the mouth & gums ■ irritation cause by dentures or orthodontic appliances ■ sore gums.

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

**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

**Do not use** ■ for more than 7 days unless directed by a dentist or doctor ■ for theething. ■ in children under 2 years of age.

**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" anesthetics. If a skin reaction occurs, stop use and seek medical help right away.

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

Directions	
Adults & children, 12 yrs of age & older	Apply to the affected area up to 4 times daily or as directed by a dentist or doctor.
Children 2 yrs of age & older	As directed by a dentist or doctor.
Children under 2 years of age	Do not use.

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

**Inactive Ingredients** ■ Clove Oil, Ethyl Alcohol, Glycerin, Polyethylene Glycol, Propylene Glycol, Sodium Saccharin, Sodium Methylparaben.

Para la versión en español del los "Drug Facts"  
visitenos en [www.germa.net](http://www.germa.net)

rev. 12/20



[www.germa.net](http://www.germa.net)

Questions or Comments: 1-305-278-0033, M-F, 9-5 Eastern

13121 SW 122 Avenue, Miami, Florida 33186

Distributed by: **Germa Products, LLC**



**Fast Pain Relief**

Net Wt.: 0.5 FL. OZ. (14.8mL.)

**ANESGERM**<sup>TM</sup>

Maximum Strength Oral Pain Reliever

GERMA<sup>®</sup>

- Fast Pain Relief for the whole family
- Easy to Apply
- Pleasant Flavor

**Fast Pain Relief**

Net Wt.: 0.5 FL. OZ. (14.8mL.)

**ANESGERM**<sup>TM</sup>

Maximum Strength Oral Pain Reliever

GERMA<sup>®</sup>

- Toothache
- Sore Gums
- Denture Irritation
- Braces Irritation

**Fast Pain Relief**

Net Wt.: 0.5 FL. OZ. (14.8mL.)

**ANESGERM**<sup>TM</sup>

Maximum Strength Oral Pain Reliever

GERMA<sup>®</sup>

- Toothache
- Sore Gums
- Denture Irritation
- Braces Irritation

**Fast Pain Relief**

Net Wt.: 0.5 FL. OZ. (14.8mL.)

**ANESGERM**<sup>TM</sup>

Maximum Strength Oral Pain Reliever

GERMA<sup>®</sup>

- Toothache
- Sore Gums
- Denture Irritation
- Braces Irritation



## ANESGERM LA MUELA FAST PAIN RELIEF

benzocaine 20% liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73635-7101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	200 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>METHYLPARABEN SODIUM</b> (UNII: CR6K9C2NHK)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CLOVE OIL</b> (UNII: 578389D6D0)	
<b>POLYETHYLENE GLYCOL 100000</b> (UNII: V46Y6OJ5QB)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73635-7101-5	1 in 1 BOX	03/29/2019	
1		14.8 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	03/29/2019	

**Labeler** - Germa Products, LLC (116626935)

Revised: 5/2023

Germa Products, LLC