

GINGICAIN FUSION- benzocaine gel

Gingi-Pak a Division of the Belport

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.

GingiCaine Fusion

Active Ingredient

Active ingredient

Benzocaine 20% w/v

Purpose

Purpose

. Oral Anesthetic

Allergy Alert

Allergy alert Do not use if patient has history of allergy to any "caine" local anesthetics or FD&C Red #40 (Strawberry only), PABA compounds, sunscreen, or any ester-type local anesthetics. **Consult a doctor promptly** if sore throat is severe; persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting • if mouth sore does not go away within 10 days • if irritation, pain, or redness persists or worsens. Avoid contact with eyes. Keep out of reach of children. If more than normal usage amount is accidentally swallowed, get medical help or contact a Poison Control Center immediately. Do not exceed recommended dosage.

Consult a doctor

Consult a doctor promptly if ■ sore throat is severe and more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting ■ mouth sore does not go away in 10 days ■ irritation, pain, or redness worsens

Avoid Excessive heat

Avoid Excessive heat Above 40°C (104°F).

Caution

Caution Store between 15 °C (59 °F) and 40 °C (104 °F).

Contraindications

Contraindications Should not be used in patients with history of hypersensitivity to ester-type local anesthetics. Do not use the product for teething or in infants and children younger than 2 years.

Directions for Use

Directions for Use 1. Dry targeted mucosal area with cotton rolls or saliva ejectors prior to application. 2. Remove luer-lock cap from syringe. 3. Securely attach the included micro needle tip onto syringe. 4. Verify flow on a mixing pad prior to application. 5. Hold plunger in palm of hand and slowly push to dispense gel to target tissue. 6. For periodontal pockets, apply a small amount to the gingival margin one quadrant at a time or directly into the pocket. 7. Keep the gel in place for at least 1 minute and spit out excess amount. 8. Dispose of used needle tip and replace luer-lock cap after application.

Dosage & Administration

Dosage & Administration • Dry targeted mucosal area with cotton rolls or saliva ejectors prior to application. • Use sterile cotton or gauze to apply the minimum amount of GINGICaine Fusion needed to induce anesthesia in the intended area. • Keep the gel in place for at least 1 minute and spit out any excess amount afterwards. • Apply up to 4 times daily or as directed by a dentist or doctor. • Do not exceed maximum recommended dosage. • Care must be taken to avoid cross-contamination between patients. • For use by adults and children 2 years of age or older.

Inactive Ingredients

Inactive Ingredients Polyethylene Glycol 400, Polyethylene Glycol 3350, Sodium Saccharin, Hemp Extract, Flavor, FD&C Red #40 (Strawberry only)

Indications

Indications Anesthesia of oral mucous membranes to minimize the pain and discomfort of ulcers, needle punctures, deep scaling procedures, and the application of matrix bands. Aids in the taking of dental impressions or intraoral radiographs in patients with an excessive gag reflex.

Keep out of reach of children

Keep out of reach of children.

Overdosage

If more than normal usage amount is accidentally swallowed, get medical help or contact a Poison Control Center immediately. Do not exceed recommended dosage.

Precautions

Precautions Dentists should avoid application to severely traumatized mucosal area which are infected or areas of the posterior pharynx that might obtund protective reflexes. Local anesthetics should be used with caution in patients with known drug sensitivities, particularly those known to be allergic to ester-type anesthetics (procaine, benzocaine, and tetracaine). Dentists should avoid contact with all local anesthetics to avoid possible sensitization.

Temper Evident Statement

**DO NOT USE IF TEMPER-EVIDENT
SLEEVE IS BROKEN.**

Uses

Uses Reduce pain or discomfort caused by • minor dental procedures including scaling and root planing • minor gum injury • canker sores • sore throat • minor mouth or gum irritation caused by dentures or orthodontic appliances. Reduces discomfort during healing of mucous membrane.

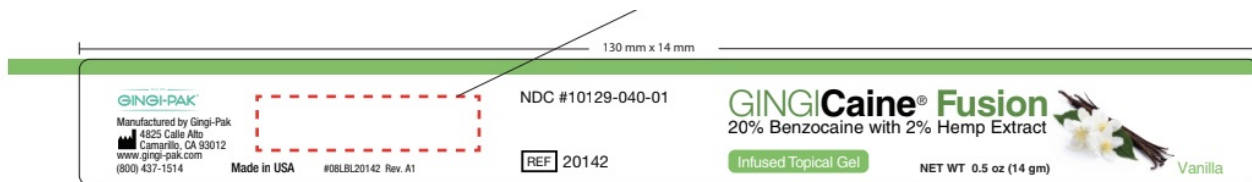
Warnings

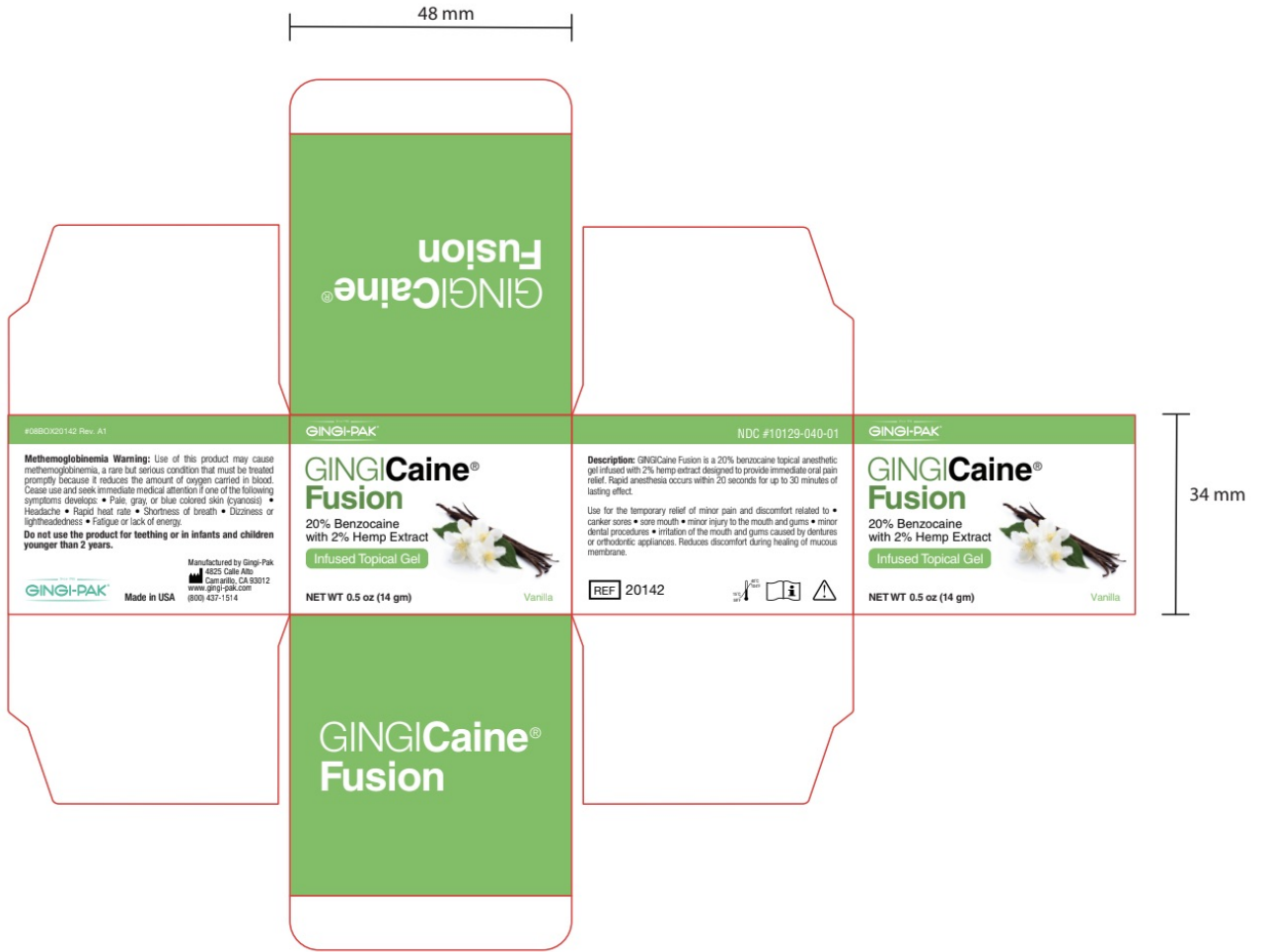
Warnings For external use only. Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Cease use and seek immediate medical attention if one of the following symptoms develops: • Pale, gray, or blue colored skin (cyanosis) • Headache • Rapid heart rate • Shortness of breath • Dizziness or lightheadedness • Fatigue or lack of energy. **Do not use in children under 2 years of age.**

Description

Description: GINGICaine® Fusion is a local anesthetic for topical application. The active ingredient is 20% Benzocaine gel infused with 2% hemp extract in a flavored polyethylene glycol base sweetened with saccharin.

Principal Display





GINGI-Caine[®]
Fusion
 Vanilla Infused Topical Gel

NOT for Injection
 Destroy After Use

1.2 mL

GINGI-PAK[®] **Made in USA**

REF 20142S **LOT** 105-156

NDC 10129-040-20 05/2023

#08LBL20142 Rev. A1

130 mm x 14 mm

<p>GINGI-PAK[®] Manufactured by Gingi-Pak 4825 Calle Alto Camarillo, CA 93012 www.gingi-pak.com (800) 437-1514</p> <p>Made in USA #08LBL20148 Rev. A1</p>	<p>NDC #10129-041-01</p> <p>REF 20148</p>	<p>GINGI-Caine[®] Fusion 20% Benzocaine with 2% Hemp Extract</p> <p>Infused Topical Gel </p> <p>NET WT 0.5 oz (14 gm) Strawberry</p>
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GINGICaine® Fusion

20% BENZOCAINE WITH 2% HEMP EXTRACT

TOPICAL ANESTHETIC GEL



GINGICaine® Fusion

TOPICAL ANESTHETIC GEL

Quick 15-20 Second Onset



Up to 30 mins of anesthesia
Immediate pain relief
Patient friendly flavor

Caution: Federal law restricts this product to sale by or on the order of a dentist. Avoid excessive heat above 40 °C (104 °F).

Since 1955
GINGI-PAK®

Manufactured by: Gingi-Pak
4825 Calle Alto
Camarillo, CA 93012
www.gingi-pak.com

0.81 OZ. (24 mL)

CONTAINS: 20 X 1.2 mL syringes and tips

Made in USA

GINGICAINE FUSION

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10129-041
Route of Administration	TOPICAL, DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	24 g in 100 g
CANNABIDIOL (UNII: 19GBJ60SN5)	2 g in 100 g

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	52 g in 100 g
POTASSIUM SODIUM SACCHARATE (UNII: 73U34YC90U)	2 g in 100 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-041-01	14 g in 1 JAR; Type 0: Not a Combination Product	06/04/2021	
2	NDC:10129-041-20	20 in 1 BOX	06/04/2021	
2		1.2 g in 1 SYRINGE, PLASTIC; 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	06/04/2021	

GINGICAINE FUSION

benzocaine gel

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Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10129-040-01	14 g in 1 JAR; Type 0: Not a Combination Product	06/04/2021	
2	NDC:10129-040-20	20 in 1 BOX	06/04/2021	
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Labeler - Gingi-Pak a Division of the Belport (008480121)**Registrant** - Jeff Nichols (008480121)**Establishment**

Name	Address	ID/FEI	Business Operations
Gingi-Pak a Division of the Belport		008480121	manufacture(10129-040, 10129-041)

Revised: 12/2021

Gingi-Pak a Division of the Belport