ORAL ANALGESIC MAXIMUM STRENGTH- benzocaine gel
LIFElabs, a Division of Atico International USA, 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.

LIFElabs, a Division of Atico International USA, INC.

Oral Analgesic (Maximum Strength)

Active Ingredient

Benzocaine 20%

Purpose

Oral pain reliever

Uses

temporarily relieves pain due to toothache, canker sores, cold sores, fever blisters, minor irritation of the mouth and gums caused by dentures or orthodontic appliances

Warnings

for temporary use only until a dentist can be consulted

Allergy alert:

do not use this product if you have a history of allergy to local anesthetics such a procaine, butacaine, benzocaine or other "caine" anesthetics.

When using this product

- do not use more than directed
- do not use for more than 7 days unless directed by a doctor/dentist
- do not use more than 4 times in a 24 hour period unless directed by a doctor/dentist

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling, rash, or fever develops

Keep out of reach of children.

In cases of overdose, get medical help or contact a Poison Control Center right away.

Directions

- remove cap and cut tip of tube on score mark
- adults and children 2 years of age and older: apply a small amount of Oral Analgesic Gel to the cavity and around gum surrounding the teeth. use up to 4 times daily or as directed by a doctor or dentist.
- children under 12 year of age: should be supervised in the use of this product
- children under 2 years of age: ask a doctor/dentist

Other information

- store at 15º to 25º (50º to 77ºF)
- This preparation is intended for use in cases of toothaches, only as a temporary expedient until a dentist can be consulted. Do not use continuously
- Lot No. and Exp. Date: see box or see crimp of tube

Inactive Ingredients

d-sorbitol solution, glycerin, peppermint flavor, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium

Questions?

Call 1-800-645-3867, Mon-Fri 8:30 AM - 5:30 PM.


12.5cm
6cm
2cm
2.5cm
3.8cm
2.5cm
3.8cm
6cm
1.3cm
2.5cm
LOT & EXP.
LIFElabs
*Compare to the active ingredient of Oragel®
MAXIMUM STRENGTH
ORAL ANALGESIC GEL
Benzocaine 20%
Provides IMMEDIATE Relief from:
Toothache Pain•Denture and Irritations•Cold and Canker Sores
LIFElabs
MAXIMUM STRENGTH Benzocaine 20%
ORAL ANALGESIC GEL
LIFElabs
NET WT .42 OZ (11.9G)
MAXIMUM STRENGTH Benzocaine 20%
ORAL ANALGESIC GEL
*This product is not manufactured by Del Pharmaceuticals, Inc, owner of the registered trademark Oragel®.
Distributed by: Atico International USA, Inc. Ft.Lauderdale,FL 33301
Made in Korea
ITEM K58M0635
LIFElabs
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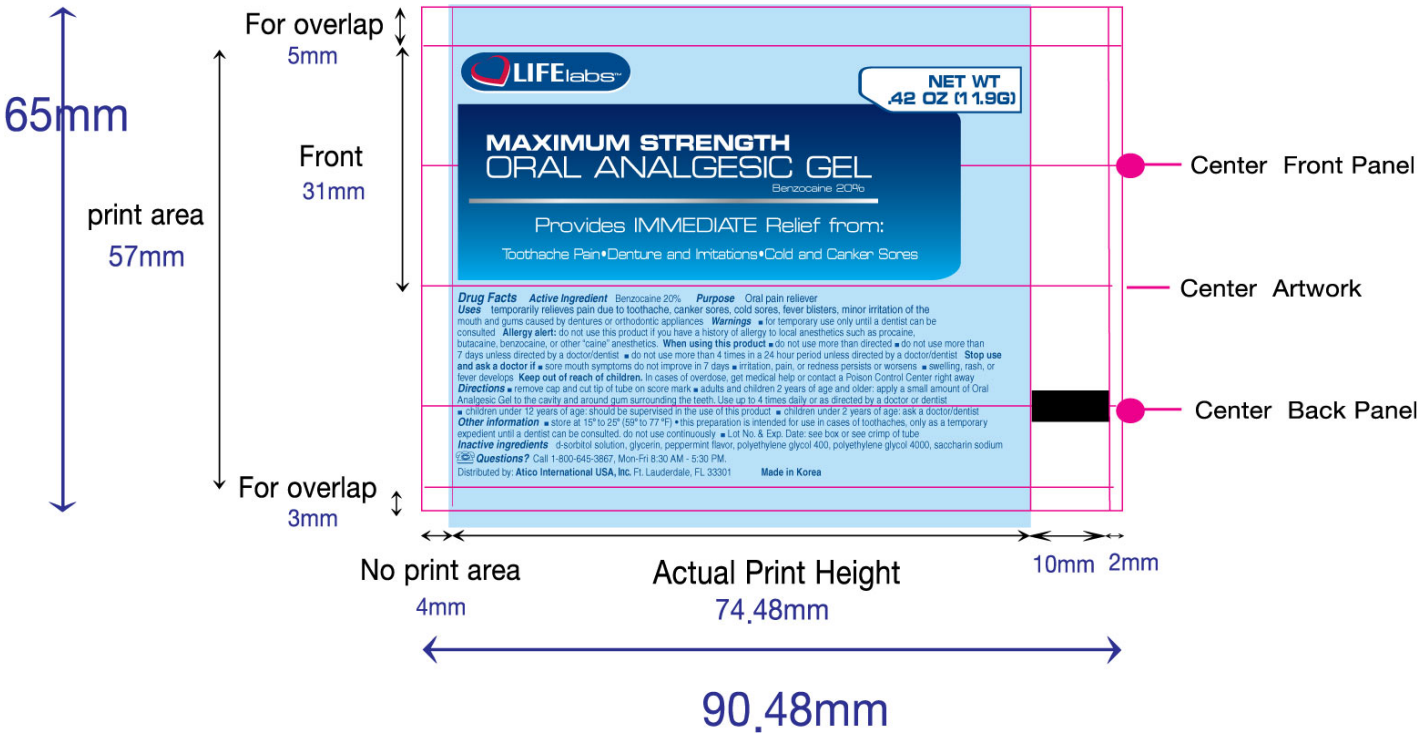

ORAL ANALGESIC MAXIMUM STRENGTH

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51852-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	200 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	

Peppermint (UNII: V95R5KMY2B)	
Polyethylene Glycol 400 (UNII: B697894SGQ)	
Polyethylene Glycol 4000 (UNII: 4R4HFI6D95)	
Saccharin Sodium (UNII: SB8ZUX40TY)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51852-101-01	1 in 1 CARTON		
1		11.9 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/01/2010	

Labeler - LIFElabs, a Division of Atico International USA, INC. (073876450)

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