ORAL GEL MAXIMUM STRENGTH- benzocaine gel
Budpak 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.

Drug Facts

Active Ingredient
Benzocaine 20%

Purpose
Anesthetic

Uses for the temporary relief of pain associated with:
- toothache
- canker sores
- cold sores
- fever blisters
- minor dental procedures

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

When using this product
- avoid contact with the eyes
- do not exceed recommended dosage

Stop using and ask a doctor
- sore mouth symptoms do not improve in 7 days
- swelling, rash or fever develops
- irritation, pain or redness persists or worsens

Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions adults and children 2 years of age and older:
- cut open tip of tube
- apply to the affected area up to 4 times daily or as directed by a dentist or doctor
- children under 12 years of age should be supervised in the use of the product
- children under 2 years of age, there is no recommended dosage except under the advice and supervision of a dentist or a doctor

Other information
- store at room temperature
- Lot No. and Exp. Date: see box or see crimp of tube

Inactive Ingredients Purified water, Glycerin, Propylene Glycol, Hydroxyethylcellulose, Carbomer, Sorbic Acid, Methylparaben, Propylparaben, FDC Yellow 5, FDC Red 40

Package Label

Budpak

*Compare to the active ingredients of Orajel®

ORAL GEL

MAXIMUM STRENGTH

ADULT TOOTHACHE PAIN RELIEF

*COMPARE CON LOS INGREDIENTES ACTIVOS DE ORAJEL®

GEL ORAL

FUERZA MÁXIMA RELEVACIÓN DE DOLOR

*COMPARE TO THE ACTIVE INGREDIENTS OF ORAJEL®

ORAL GEL

MAXIMUM STRENGTH PAIN RELIEF

Benzocaine 20%

NET WT 0.5 OZ (14g)

Budpak

ORAL GEL

MAXIMUM STRENGTH

ADULT TOOTHEACHE PAIN RELIEF

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MAXIMUM STRENGTH PAIN RELIEF

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*This product is not manufactured or distributed by Del Laboratories, Inc., owner of the registered trademark Orajel®.

Distributed by BUDPAK INC., Ronkonkoma, NY 11779 Made in China

Budpak

MAXIMUM STRENGTH

ORAL GEL

PAIN RELIEF

ORAL GEL MAXIMUM STRENGTH

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27293-012
Route of Administration	TOPICAL		

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**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBIC ACID (UNII: X045WJ989B)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:27293-012-01	1 in 1 BOX		
1	NDC:27293-012-14	14 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	02/01/2010	

Labeler - Budpak Inc. (183224849)

Establishment

Name	Address	ID/FEI	Business Operations
Ausmetics Daily Chemicals (Guangzhou) Co. Ltd.		529836561	manufacture