BABY TEETHING ORAL PAIN RELIEVER - 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 7.5%

Purpose
Anesthetic

Uses temporarily relieves sore gums due to teething in infants and children 4 months and older

Warnings

- **Allergy alert:** do not use this product if your baby has a history of allergy to local anesthetics such as procaine, butacaine or other "caine" anesthetics

Do not use

- for more than 7 days unless told to do so by a physician
- more than directed

When using this product

- fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your physician

Stop using and ask a dentist or physician

- sore mouth symptoms do not get better in 7 days
- irritation, pain or redness does not go away
- swelling, rash or fever develops

Keep out of reach of children. In case of overdose or allergic reaction contact a Poison Control Center right away

Directions

- wash your hands
- use your fingertip or cotton applicator to apply a small pea-size amount of Budpack Baby Teething Gel Medicine.
- Apply to affected area up to 4 times daily or as directed by a dentist or physician.
- for infants under 4 months of age, ask a doctor

Other information

- Store at 15 to 25 C (59-77F)

Inactive Ingredients Purified water, Glycerin, Propylene Glycol, Hydroxyethylcellulose, Carbomer,

Sorbic Acid, Methylparaben, Propylparaben, FDC Yellow 5, FDC Red 40

Package Label

ORAL PAIN RELIEVER FOR TEETHING

BABY TEETHING GEL

Benzocaine 7.5%

*COMPARE CON LOS INGREDIENTES ACTIVOS DE BABY ORAJEL®

GEL PARA DENTICIÓN DEL BEBÉ

ALIVIADOR ORAL PARA EL DOLOR DE LA DENTICIÓN

Benzocaína 7.5%

*COMPARE TO THE ACTIVE INGREDIENTS OF BABY ORAJEL®

BABY ORAL PAIN RELIEVER FOR TEETHING TEETHING GEL Benzocaine 7.5%

NET WT 0.5 oz. (14g)

Budpak

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Do not use ■ for more than 7 days unless told to do so by a physician ■ more than directed.

When using this product ■ fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms do not go away, advise your physician.

Stop use and ask a dentist or physician if ■ sore mouth symptoms do not get better in 7 days ■ irritation, pain or redness does not go away ■ swelling, rash or fever develops.

Keep out of reach of children. In cases of overdose or allergic reaction, get medical help or contact a Poison Control Center right away.

Directions

■ do not use if tube tip is cut prior to opening ■ wash hands ■ cut open tip of tube on score mark
■ use your fingertip or cotton applicator to apply a small pea-size amount of Budpak Baby Teething Gel Medicine.
■ apply to affected area up to 4 times daily or as directed by a dentist or physician.
■ for infants under 4 months of age, ask a doctor.

Other information

■ Store at 15° to 25° C (59° to 77° F)

Inactive Ingredients Purified Water, Glycerin, Propylene Glycol, Hydroxyethylcellulose, Carbomer, Sorbic Acid, Methylparaben, Propylparaben, FD & C Yellow #5, FD & C Red #40.

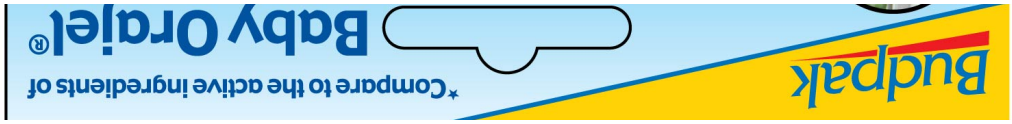
*This product is not manufactured or distributed by Del Laboratories, Inc., owner of the registered trademark Baby Orajel®.

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

Budpak

BABY ORAL PAIN RELIEVER FOR TEETHING TEETHING GEL Benzocaine 7.5%

1/2 oz. Size



BABY TEETHING ORAL PAIN RELIEVER

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27293-013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	7.5 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:27293-013-01	1 in 1 BOX		
1	NDC:27293-013-14	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	05/01/2010	

Labeler - Budpak Inc. (183224849)

Establishment

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

Revised: 5/2010

Budpak Inc.