BUDPAK 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.

Budpak Baby Teething Oral Pain Reliever Gel

Active Ingredient

Benzocaine 7.5%

Purpose

Oral pain reliever

Use

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, benzocaine 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 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 safety seal is broken
- wash hands
- break seal on tube
- 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°C to 25 °C (59°F to 77°F)
- Lot No. & Exp. Date: see crimp of tube

Inactive Ingredients

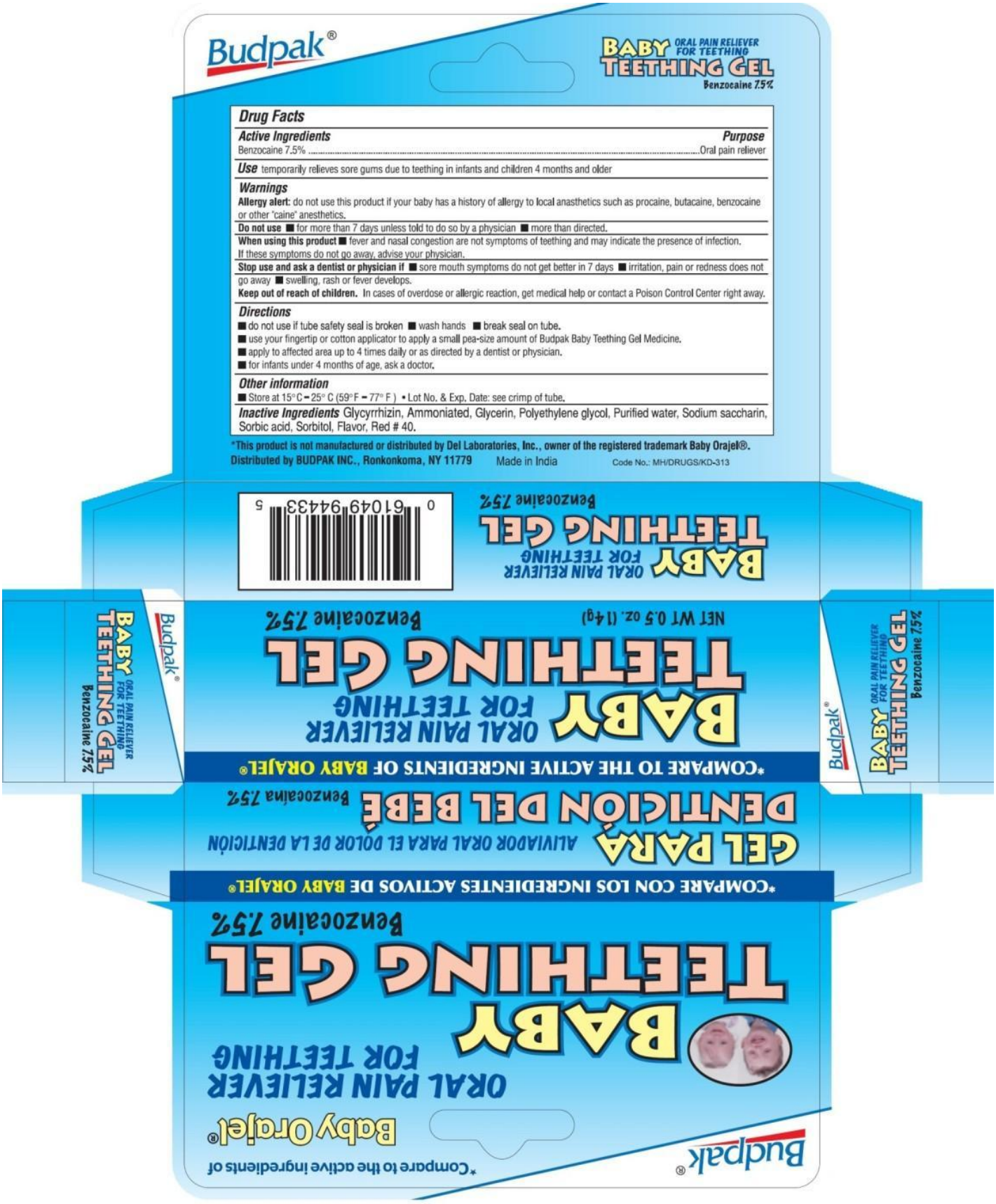
Glycyrrhizin Ammoniated, Glycerin, Polyethylene glycol, Purified water, Sodium saccharin, Sorbic acid, Sorbitol, Flavor, Red #40.

PRINCIPAL DISPLAY PANEL

BUDPAK BABY TEETHING PAIN RELIEVER GEL

Benzocaine 7.5%

NET WT 0.5 OZ. (14 g)



BUDPAK BABY TEETHING ORAL PAIN RELIEVER

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27293-015
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**
GLYCYRRHIZIN, AMMONIATED (UNII: 3VRD35U26C)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITOL (UNII: 506T60A25R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:27293-015-01	1 in 1 BOX		
1	NDC:27293-015-14	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	12/26/2013	

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-015)

Revised: 12/2013 Budpak Inc.