BUDPAK ORAL 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.

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 this product 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:

- break seal on tube
- apply to the affected area up to 4 times daily or as directed by a dentist or a 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 crimp of tube.

Inactive Ingredients

Ammonium Glycyrrhizate, Polyethylene glycol, Saccharin sodium, Sorbic acid, Flavor

PRINCIPAL DISPLAY PANEL

ORAL MAXIMUM STRENGTH PAIN RELIEF GEL

Benzocaine 20%

Anesthetic

NET WT 0.5 OZ (14 g)

BUDPAK ORAL MAXIMUM STRENGTH

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:27293-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.2 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCYRRHIZIN, AMMONIATED (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-019-01	1 in 1 BOX		
1	NDC:27293-019-14	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	06/10/2013	

Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-019)

Revised: 6/2013 Budpak Inc.