NENE DENTE- benzocaine liquid Menper Distributors, 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 Purpose

Benzocaine 7%...... Pain Reliever

Pain Reliever

□**Uses**□ For the temporary relief of sore gums due to teething in infants and children 4 months of age and older.

Warnings: Do not exceed recommended dosage.

Keep this and all drugs out of the reach of children. [Fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your physician.

Do not Use:

- for more than 7 days unless directed but a physician
- if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics

Stop Use and see a Doctor

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

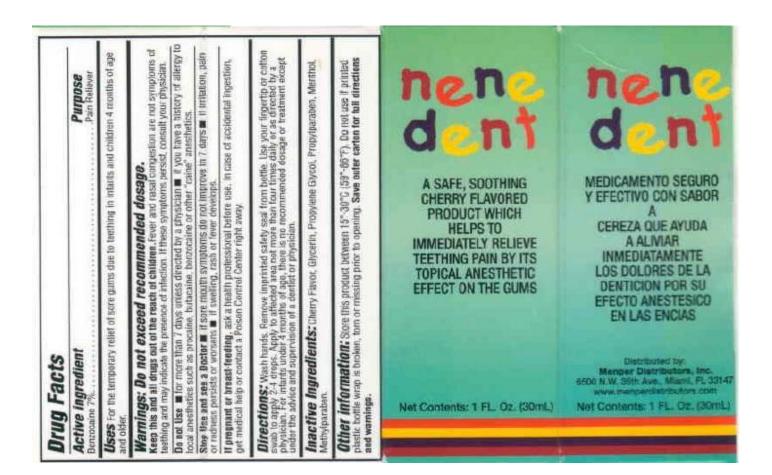
Keep out of reach of children.

If pregnant or breast-feeding, <code>[ask a health professional before use. In case of accidental ingestion, get medical help or contact a Posion Control Center right away.</code>

Directions: I wash hands. Remove imprinted safety seal from bottle. Use your fingertip or cotto swab to apply 2-4 drops. Apply to affected area not more than four times daily or as directed by a physician. For infants under 4 months of age, ther is no recommended dosage or treatment execpt under the advice and supervision of a dentist or physician.

Other information: Istore this product between 15-30 C (59-86 F). Do not use if printed plastic bottle wrap is broken, toen or missing prior to opening. Isave outer carton for full directions and warnings.

□ **Inactive ingredients**: □ Cherry flavor, Glycerin, Propylene Glycol, Propylparaben, Menthol, Methylparaben.



NENE DENTE

benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-335
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	2.1 mg in 30 mL

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
MENTHOL (UNII: L7T10EIP3A)			
METHYLPARABEN (UNII: A2I8 C7HI9 T)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:53145-335-01	1 in 1 CARTON				
1	30 mL in 1 BOTTLE				
Marketing Information					
Marketing Category	Application Number or Monog	raph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356		0 1/0 1/20 14		

Labeler - Menper Distributors, Inc (101947166)

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