BABY ANESTENKA- benzocaine liquid Menper Distributors

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%(w/w)......Oral Anesthetic/Analgesic

Oral Anesthetic/Analgesic

□Uses □ temporarily relieves sore gums due to teething ininfants and children 4 months of age and older.

IFor oral use only.

Allery Alert: Ido not use tihs product if you have a history of allergy to local anesthetics such as procaine, butaine, benzocaine or other "caine" anesthetics.

Fever and nasal congestion are not symptoms of teething and may indicate the presence of infection. If these symptoms persist, consult your doctor or dentist. **A fever could be a sign of serious condition.**

Stop use and ask a doctor or dentist if

- oral pain does not get better in 7 days
- irritation, pain, or redness does not go away
- rash or fever develops
- redness or swelling is present

Keep out of reach of children. In case of accidental oveerdose, get medical help or contact a Poison Control Center right away.

Directions Do not use more than directed. Wash hands. Remov imprinted safety seal from bottle. Use your fingertip or cotton swab to apply 2-4 drops. Apply to affected area not more than four tims daily or as directed by a physician. For infants under 4 months of age, there is no recommended dosage or treatment execpt under the advice and supervision of a dentist or physican.

Other information Store at a controlled room temperature between 15 an 30 c (59-86 F)

Tamper Evident Feature: Ido not use if imprinted safety seal over bottle cap is torn, broken or missing prior to opening. Isave outer carton for full instructions and warnings.

Questions? 1-800-560-5223 M-F 9 AM to 4 PM Eastern.

Inactive ingredients ICherry Flavor, Glycerin, Menthol, Methylparaben, Propylene Glycol, Propylparaben.



Drug Facts Ver prospecto para información en Español

 Active ingredient
 Purpose

 Benzocaine 7% (w/w)
 Oral Anesthetic/Analgesis

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Warnings

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Stop use and ask a doctor or dentist if oral pain does not get better in 7 days in irritation, pain, or redness does not go away in rash or fever develops in redness or swelling is present

Keep out of the reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

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Distributed by:

Menper Distributors, Inc.
6500 N.W. 35th Avenue Miami, FL 33147
www.menperdistributors.com

BABY ANESTENKA

benzocaine liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53145-902

Route of Administration TOPICAL

Active Ingredient/Active Moiety

PROPYLPARABEN (UNII: Z8IX2SC1OH)

Ingredient NameBasis of StrengthStrengthBENZO CAINE (UNII: U3RSY48JW5) (BENZO CAINE - UNII: U3RSY48JW5)BENZO CAINE2.1 mg in 30 mL

Inactive Ingredients Ingredient Name Strength GLYCERIN (UNII: PDC6A3C0OX) MENTHOL (UNII: L7T10EIP3A) METHYLPARABEN (UNII: A2I8C7HI9T) PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

Pac	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:53145-902-12	1 in 1 CARTON								
1	30 mL in 1 BOTTLE								
Marketing Information									
Marketing Category	Application Number or Monog	raph Citation	Marketing Start Da	te Marketing End Date					
OTC monograph not final	part356		0 1/0 1/20 14						

Labeler - Menper Distributors (101947166)

Revised: 1/2015 Menper Distributors