

FAMILY DOLLAR ORAL PAIN RELIEF- benzocaine liquid
Family Dollar Services 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.

5820388 Family Wellness Max Str Oral Pain Relief

Drug Facts

Active ingredient

Benzocaine 20% (W/W)

Purpose

Oral anesthetic

Use

Temporarily relieves pain associated with the following mouth and gum irritations:

- toothache
- sore gums
- canker sores
- braces
- minor dental procedures

Warnings

Methemoglobinemia warning: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin(cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use

- more than directed
- for more than 7 days unless told to do so by a dentist or doctor
- for teething
- in children under 2 years of age

Stop use and ask a doctor if

- swelling, rash or fever develops
- irritation, pain or redness persists or worsens

- symptoms do not improve in 7 days
- allergic reaction occurs

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

Directions

Adults and children 2 years of age and older:

- apply to affected area using applicator tip
- use up to 4 times daily or as directed by a dentist or doctor
- children under 12 years of age should be supervised in the use of this product

children under 2 years of age: do not use

Other information

- do not use if package has been opened
- store at 20 - 25 C (68-77F)

Inactive ingredients Benzyl Alcohol, D&C Yellow no. 10, FD&C Blue no. 1, FD&C Red no. 40, Methylparaben, Natural and Artificial Flavor, Polyethylene Glycol, Propylene Glycol, Sodium Saccharin, Water

MADE IN CANADA

DISTRIBUTED BY:

MIDWOOD BRANDS, LLC

10611 MONROE RD.

MATTHEWS, NC 28105



FAMILY WELLNESS

MAXIMUM STRENGTH

Oral Pain Relief

20% Benzocaine

Liquid Anesthetic

0.5 FL OZ (14.7 mL)

FAMILY DOLLAR ORAL PAIN RELIEF			
benzocaine liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-388
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	20 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	orange (orange to reddish orange)	Score	
Shape		Size	
Flavor	PINEAPPLE (Pina Colada Flavor 26041)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-388-82	1 in 1 CARTON	08/01/2013	03/23/2023
1		14.7 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/01/2013	

Labeler - Family Dollar Services Inc. (024472631)

Registrant - Lornamead (078584069)

Establishment

Name	Address	ID/FEI	Business Operations
CSR Cosmetic Solutions Inc.		243501959	manufacture(55319-388)

Revised: 6/2023

Family Dollar Services Inc.