

REXALL MAXIMUM STRENGTH- benzocaine liquid

Rexall

5820346 DG Max Str OP Relief Liq

Active ingredient

Benzocaine 20.0%Purpose: Oral pain reliever

Uses

Temporarily relieves pain associated with the following mouth irritations toothache sore gums canker sores braces minor dental procedures

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

When using this product

- avoid contact with eyes
- do not exceed recommended dosage
- Do not use more than directed for more than 7 days unless directed by a dentist or doctor.

Stop use and ask a doctor if sore mouth symptoms do not improve in 7 days, swelling, rash or fever develops, irritation, pain or redness persists or worsens swelling rash or fever developes

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: ask a dentist or doctor.

Other Information

Do not use if package has been opened

Store at 20-25°C (68-77°F)

Inactive ingredients

Benzyl Alcohol, D&C Yellow 10, FD&C Blue 1, FD&C Red 40, FD&C Yellow 5,

Methylparaben, Flavor, Polyethylene Glycol, Propylene Glycol, Sodium Saccharin, Water

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benzocaine liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-346
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 mL
Inactive Ingredients			

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	orange (dark orange/red to sl brown)	Score	
Shape		Size	
Flavor	MINT (Mint)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-346-79	1 in 1 CARTON	02/01/2023	
1		14.7 mL 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 Drug	M022	01/01/2015	

Labeler - Rexall (068331990)

Registrant - Lornamead Products (119559733)

Establishment

Name	Address	ID/FEI	Business Operations
HK KOLMAR CANADA, INC		243501959	manufacture(55910-346) , pack(55910-346)