HEB HEBUDDY- fluoride paste, dentifrice HEB

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.

Drug Facts

Active ingredient

Sodium Fluoride 0.24%Purpose: Anticavity

Uses

Helps protect against caviites

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children under 6 years of age.

Directions

Adults and children 2 years of age and older: brush teeth thorughly preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Do not swallow

To minimize swallowing use a pea-sized amount in children under 6

Supervise childrens brushing until good habits are established

Children under 2 years of age: consult a dentist or doctor.

Other Information

Store in a cool dry place. Keep tube capped when not in use.

Inactive ingredients

Sorbitol, Water, Hydrated Silica, Glycerin, Cellulose Gum, PEG-12, Flavor, Sodium Benzoate, Sodium Saccharin, Cocamidopropyl Betaine, Mica, Titanium Dioxide, Red 40

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:37808-192

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SORBITOL (UNII: 506T60A25R)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF30 11 KX)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

Product Characteristics				
Color	pink	Score		
Shape		Size		
Flavor	WATERMELON (Watermelon mint)	Imprint Code		
Contains				

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:37808-192-00	12 in 1 CASE			
1	NDC:37808-192-02	120 g in 1 TUBE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/0 1/20 12	

Labeler - HEB (007924756)

Registrant - Lornamead (126440440)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(37808-192), pack(37808-192)

Revised: 1/2013 HEB