MEDIF TOOTH- silicon dioxide, alcloxa paste, dentifrice MEDIF CO.,LTD

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENT

Active ingredients: SILICON DIOXIDE 14.0%, ALCLOXA 0.05%

INACTIVE INGREDIENT

Inactive ingredients: D-Sorbitol Solution, Propolis Powder, Concentrated Glycerin, Sodium Cocoyl Glutamate, Xantangum, L-Menthol, Peppermint Oil, Charcoal, Grapefruit Seed Extract, Hydroxyapatite, Xylitol, Anetol Oil, Glucosyl Stevia, Chamomile Extract, Eucalyptus Extract, Sage Extract, Aloe Extract, Glycyrrhiza Extract Powder, Silver foil, Water

PURPOSE

Purpose: Anticarries

WARNINGS

Warnings: Keep out of the reach of children under 6 years of age. 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

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

Uses

Uses: Helps protect against cavities.

Directions

Directions:

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician

Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

Children under 2 years: Ask a dentist or physician

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





silicon dioxide, alcloxa paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72346-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) (SILICON DIO XIDE - UNII: ETJ7Z6 XBU4)	SILICON DIOXIDE	18.20 g in 130 g	
ALCLOXA (UNII: 18B8O9DQA2) (ALLANTOIN - UNII:344S277G0Z)	ALCLOXA	0.06 g in 130 g	

Inactive Ingredients	
Ingredient Name	Strength
PROPOLIS WAX (UNII: 6 Y8 XYV2NOF)	

	Packaging			
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:72346-010-02	1 in 1 CARTON	05/01/2018	
	NDC:72346-010-01	130 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2018	

Labeler - MEDIF CO.,LTD (694955391)

Registrant - MEDIF CO.,LTD (694955391)

Establishment				
Name	Address	ID/FEI	Business Operations	
MEDIF CO.,LTD		694955391	manufacture(72346-010)	

Revised: 5/2018 MEDIF CO.,LTD