FINEFRA BLACK TOOTH- silicon dioxide, alcloxa paste, dentifrice
Jewoo Medical 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: Silica 15.00%, Alcloxa 0.16%

INACTIVE INGREDIENT

Inactive ingredients:

Sorbitol, Water, Glycerin, Sodium Cocoyl Glutamate, Cellulose Gum, Mentha Piperita (Peppermint) Oil, Sophora Angustifolia Root Extract, Charcoal Powder, Xylitol, Menthol, Stevioside, Chamaecyparis Obtusa Oil, Eucalyptus Globulus Leaf Oil, Carvone, Anethole, Hydroxyapatite, Glycyrrhiza Glabra (Licorice) Root Extract, Aloe Barbadensis Leaf Extract, Gentiana Lutea Root Extract, Lavandula Angustifolia (Lavender) Flower Extract, Camellia Sinensis Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Salvia Officinalis (Sage) Leaf Extract, Chitosan, Chamomilla Recutita (Matricaria) Flower Extract, Propolis Extract, Scutellaria Baicalensis Root Extract, Silver, Mika, Commiphora Myrrha Oil, Krameria Triandra Root Extract

PURPOSE

Purpose: Anticavity

WARNINGS

Warnings:

Keep out of the reach of children under 6 years of age.
If you accidentally swallow more than used for brushing, Seek professional help or contact a poison control center immediately

KEEP OUT OF REACH OF CHILDREN

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

Uses

Uses:

Aids in the prevention of cavities, plaque, and gingivitis.

Directions

Directions:

Adults and children 2 yrs. older: Brush teeth thoroughly after meals or at least twice a day, or use as directed by a dentist or physician. Do not swallow. Children under 6 yrs.: To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established. Children under 2 yrs.: Ask a dentist or physician.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

FINEFRA BLACK TOOTH

silicon dioxide, alcloxa paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69653-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4)	SILICON DIOXIDE	15.0 g in 100 g
ALCLOXA (UNII: 18B8O9DQA2) (ALLANTOIN - UNII:344S277G0Z)	ALCLOXA	0.16 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69653-100-02	1 in 1 CARTON	12/01/2019	
1	NDC:69653-100-01	100 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		12/01/2019	

Labeler - Jewoo Medical Co,.Ltd (689512541)

Registrant - Jewoo Medical Co,.Ltd (689512541)

Establishment

Name	Address	ID/FEI	Business Operations
Korea Life Science Co.,ltd		694914835	manufacture(69653-100)

Revised: 2/2020 Jewoo Medical Co,.Ltd