FINEFRA CLINIC TOOTH 135G- sodium monoflurophosphate paste, dentifrice
Jewoo Medical Co,.Ltd

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.

ACTIVE INGREDIENT

Active ingredients: Sodium Monofluorophosphate 0.76%

INACTIVE INGREDIENT

Inactive ingredients:

D-Sorbitol Solution, Silica, Purified Water, Dentaltype Silica, Glycerin, Mika, Sodium Cocoyl Glutamate, Mentha Piperita (Peppermint) Oil, Carboxymethylcellulose Sodium, Stevioside, Charcoal Powder, Menthol, Xylitol, Allantoine Chlorohydroxy Aluminum, Aminocaproic Acid, Glycyrrhiza, Glabra (Licorice) Root Extract, Gentiana Lutea Root Extract, Sophora, Flavescens Root Extract, Lavandula Angustifolia Extract, Rhatany Tincture, Rosemary Extract, Mastic Oil, Myrrh Tincture, Salvia Officinalis (Sage) Extract, Anethole, Aloe Barbadensis Leaf Extract, Eucalyptus Oil, Chamomilla Recutita (Matricaria) Flower Extract, Chitosan, Chamaecyparis Obtusa Oil, Propolis Extract, Scutellaria Root Extract, Carvone, Silver, Hydroxyapatite

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 CLINIC TOOTH 135G

sodium monoflurophosphate paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69653-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.02 g in 135 g

Inactive Ingredients	
Ingredient Name	**Strength**
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69653-040-02	1 in 1 CARTON	05/01/2018	
1	NDC:69653-040-01	135 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
OTC monograph final	part355	05/01/2018	

Labeler - Jewoo Medical Co,.Ltd (689512541)

Registrant - Jewoo Medical Co,.Ltd (689512541)

Establishment

Name	Address	ID/FEI	Business Operations
NEO-MEDICALFARM CO.,LTD		694914835	manufacture(69653-040)

Revised: 11/2018 Jewoo Medical Co,.Ltd