FINEFRA 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, Mica, Sodium Cocoyl Glutamate, Mentha Piperita, (Peppermint) Oil, Cellulose Gum, Stevioside, Menthol, Xylitol, Glycyrrhiza, Uralensis (Licorice) Root Extract, Gentiana Lutea Root Extract, Sophora Flavescens Root Extract, Lavandula Angustifolia (Lavender) Extract, Rosmarinus Officinalis, Pistacia Lentiscus (Mastic) Gum, Salvia Officinalis, (Sage) Extract, Aloe Barbadensis Leaf Extract, Eucalyptus Globulus Leaf Oil, Chamomilla Recutita (Matricaria) Flower Extract, Chitosan, Chamaecyparis, Obtusa Oil, Propolis Extract, Charcoal Powder, Scutellaria Root Extract, Anethole, Hydroxyapatite, Silver

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 TOOTH

silicon dioxide, alcloxa paste, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69653-050

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 | 15.0 g in 100 g |
| ALCLOXA (UNII: 18B8O9DQA2) (ALLANTOIN - UNII:344S277G0Z) | ALCLOXA | 0.16 g in 100 g |

Inactive Ingredients

| mactive ingredients | |
|-----------------------------|----------|
| Ingredient Name | Strength |
| SORBITOL (UNII: 506T60A25R) | |
| Water (UNII: 059QF0KO0R) | |

Packaging

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|------------|------------------|--|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:69653-050-02 | 1 in 1 CARTON | 05/01/2018 | |
| 1 | NDC:69653-050-01 | 100 g in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

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|----------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other | | 05/01/2018 | |
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Labeler - Jewoo Medical Co,.Ltd (689512541)

Registrant - Finefrajapan Co.,ltd. (693542047)

| Establishment | | | | |
|-------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| NEO-MEDICALFARM CO.,LTD | | 694914835 | manufacture(69653-050) | |

Revised: 11/2018 Jewoo Medical Co, Ltd