**BIS II TOOTH- precipitated calcium carbonate, tocopherol acetate, aluminium chlorohydroxy allantoinate, dibasic calcium phosphate hydrate 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.*

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**Drug Facts**

Precipitated Calcium Carbonate
Tocopherol Acetate
Dibasic Calcium Phosphate Hydrate
Aluminium Chlorohydroxy Allantoinate

Glycerin
D-Sorbitol Solution
Silica
Carboxymethylcellulose Sodium
Sodium Cocoyl Glycinate
Mica
Chitosan
Xylitol
Steviol Glycoside
L-Menthol
Glycyrrhiza Extract
Sophora Flavescens Extract
Scutellaria Baicalensis Root Extract
Salvia Officinalis (Sage) Extract
Calendula Officinalis Flower Extract
Gentiana Lutea Root Extract
Rosmarinus Officinalis (Rosemary) Extract
Aloe Barbadensis Leaf Extract
Citrus Paradisi (Grapefruit) Seed Extract
Lavandula Angustifolia (Lavender) Extract
Propolis Extract
Eucalyptus Globulus Leaf Oil
Chamaecyparis Obtusa Oil
Pistacia Lentiscus (Mastic) Gum
Anethole
fravor
Silver
Activated Carbon
Hydroxyapatite
Water

Aids in the prevention of cavities, plaque, and gingivitis

keep out of reach of the children

Adults and children 2 yrs. older: Brush teeth thoroughly after meals or at least twice a day, or use as directed by a tentist or physician. Do not shallow.

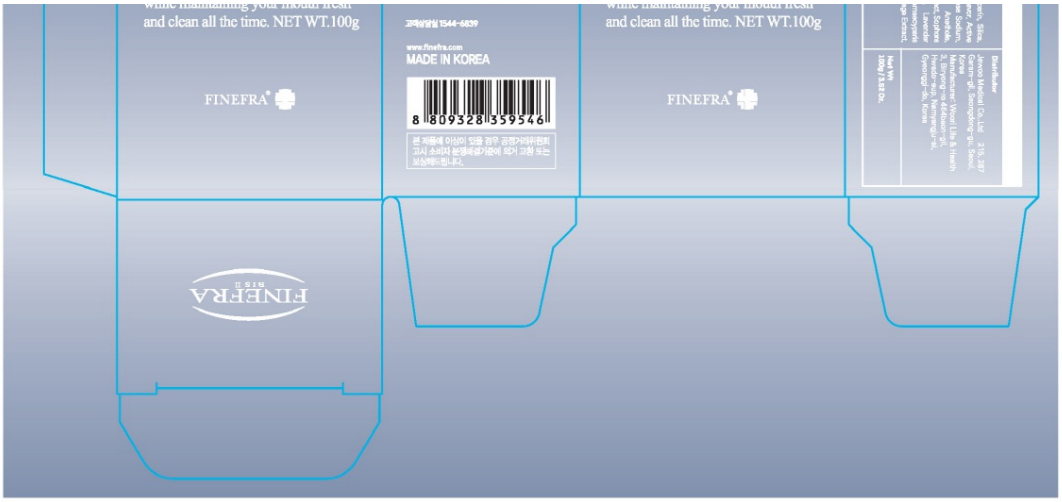
Children under 6 yrs.: To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established.

Children under 2 yrs.: Ask a dentist or physician.

Keep out of 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.

for external use only





# BIS II TOOTH

precipitated calcium carbonate, tocopherol acetate, aluminium chlorohydroxy allantoinate, dibasic calcium phosphate hydrate paste, dentifrice

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69653-201 |
| **Route of Administration** | DENTAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) (ANHYDROUS DIBASIC CALCIUM PHOSPHATE - UNII:L11K75P92J) | DIBASIC CALCIUM PHOSPHATE DIHYDRATE | 0.04 g in 100 g |
| **CALCIUM CARBONATE** (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB) | CALCIUM CATION | 0.1 g in 100 g |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1) | .ALPHA.-TOCOPHEROL | 0.04 g in 100 g |
| **ALCLOXA** (UNII: 18B8O9DQA2) (ALCLOXA - UNII:18B8O9DQA2) | ALCLOXA | 0.04 g in 100 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:69653-201-01 | 100 g in 1 TUBE; Type 0: Not a Combination Product | 01/01/2026 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 01/01/2026 | |

## Labeler - Jewoo Medical CO.,LTD (689512541)

## Registrant - Jewoo Medical CO.,LTD (689512541)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Jewoo Medical CO.,LTD | | 689512541 | manufacture(69653-201) |

Revised: 2/2026 Jewoo Medical CO.,LTD