28TAK DOUX TOOTH- silicon dioxide paste, dentifrice ELMEDITEC 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 8.0%

INACTIVE INGREDIENT

Inactive ingredients:

D-Sorbitol Solution, Water, Concentrated Glycerin, Xantangum, Sodium Cocoyl Glutamate, Raspberry Flavor, Black Current Flavor, Xylitol, Chitosan, Rosemary Extract, Matricaria Extract, Eucalyptus Extract, Sage Extract, Aloe Extract, Green Tea Extract, Ascorbic Acid, Tocopherol Acetate

PURPOSE

Purpose: Anticavity

WARNINGS

Warnings:

(1) Do not swallow and rinse mouth thoroughly after use (2) If you experience any problems with your gums or mouth during use, discontinue use and consult your doctor. (3) For children under 6 years of age, use small amounts of toothpaste. And use it under the supervision of a guardian to avoid sucking or swallowing. (4) Consult a physician or dentist immediately if a child under 6 years old has swallowed large quantities. (5) Keep out of the reach of children under 6 years of age.

KEEP OUT OF REACH OF CHILDREN

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

Uses

Uses:

Keep your teeth white and strong. Keep your mouth clean. Refresh the inside of the mouth. To prevent tooth decay and remove bad breath. Increase esthetic effect. Removal of plaque (anti-plaque)

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







"우리 아기의 첫 치약"









Drug Facts

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SILICON DIOXIDE 8.0%

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Inactive Ingredients
D-Sorbits Solution, Water Concentrated Glycerin, Xiantangum, Sodium
Cocoy (Butamate, Raspberry Pisco, Black Current Ravor, Xylliot, Chitosa
Rosenary Estract, Maricaria Estract, Eucalyptus Estract, Sagie Estract,
Aloe Estract, Green Tea Estract, Assorbic Acid, Tocopherol Acetate

Questions

32-1688-2849 www.28tak.com

Manufactured for Team ELMEDITEC CO.,LTD. 782, Sintanjin-ro, Daedeokgu, Daejeon, 10078, Korea

Manufactured by Dongil Pharmaceutical Co., Ltd. 26, Rinosandan-gil, Maengdong-myeon, Eumseong-gun, Chungbuk, Kore

60g / 2.12 Fl. Oz.

▶ 부드러운 천연향과 저자극성 원료만을 사용합니다. 우리아기의 소중한 첫니를 생각하며, 자극적이지 않는 은은한 천연베리향 으로 거부감이 없습니다.

DOUX 도우치약

Baby

TOOTHPASTE

이엘치과병원 의료진 공동 연구·기술 개발



천 연 유 래 성 분 불 소 무 첨 가

60g

이엘치과병원 의료진 공동 연구·기술 개발

www.28tak.com



silicon dioxide paste, dentifrice

| Product Information | l |
|----------------------------|---|
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:72440-010

Route of Administration ORAL

Active Ingredient/Active Moiety

| -1001/ 0 111 8 1 0 0101111111 011/ 0 1112010 0 | | | |
|---|-------------------|---------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) (SILICON DIO XIDE - UNII: ETJ7Z6 XBU4) | SILICON DIOXIDE | 4.8 g in 60 g | |

Inactive Ingredients

| mactive ingredients | |
|----------------------------|----------|
| Ingredient Name | Strength |
| Water (UNII: 059QF0KO0R) | |
| Xylitol (UNII: VCQ006KQ1E) | |

Packaging

| • | 1 deading | | | |
|---|--|---------------------|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:72440-010-02 | 1 in 1 CARTON | 07/01/2018 | |
| 1 | NDC:72440-010-01 60 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 | | 07/01/2018 | |
| | | | |

Labeler - ELMEDITEC CO.,LTD (694771074)

Registrant - ELMEDITEC CO.,LTD (694771074)

| Establishment | | | | |
|-------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| ELMEDITEC CO.,LTD | | 694771074 | manufacture(72440-010) | |

Revised: 7/2018 ELMEDITEC CO.,LTD