28TAK CLAIR TOOTH- silicon dioxide, sodium monofluorophosphate 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%, SODIUM MONOFLUOROPHOSPHATE 0.22%

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) Contains 290ppm of fluoride. (2) Do not swallow and rinse mouth thoroughly after use (3) If you experience any problems with your gums or mouth during use, discontinue use and consult your doctor.
(4) 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. (5) Consult a physician or dentist immediately if a child under 6 years old has swallowed large quantities. (6) 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



28TAK CLAIR TOOTH

silicon dioxide, sodium monofluorophosphate paste, dentifrice

| Product Information | ion | | | | | | | | |
|--|------------------|---------------------------------|---------|----------------------|----------|--------------------|-------------------|--|--|
| Product Type | | HUMAN OTC DRUG | Ite m C | Code (Source) | | NDC:72440-020 | | | |
| Route of Administrat | ion | ORAL | | | | | | | |
| | | | | | | | | | |
| Active Ingradiant | Active Mai | a 4 | | | | | | | |
| Active Ingredient/Active Moiety Basis of Basis o | | | | | | | | | |
| Ingredient Name | | | | | | ength | Strength | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) (SILICON DIOXIDE - UNII:ETJ7Z6XBU4) | | | | | | N DIO XIDE | 4.8 g in 60 g | | |
| SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | | | | | | DE ION | 0.13 g in 60 g | | |
| | | | | | | | | | |
| Inactive Ingredients | | | | | | | | | |
| | Iı | ngredient Name | | | Strength | | | | |
| Water (UNII: 059QF0KO0R) | | | | | | | | | |
| Xylitol (UNII: VCQ006KQ1E) | | | | | | | | | |
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| Packaging | | | | | | | | | |
| # Item Code | | Package Description | | Marketing Start Date | | Marketing End Date | | | |
| | 1 in 1 CARTON | | J | 07/01/2018 | | | | | |
| 1 NDC:72440-020-01 | ou g III I I UBE | ; Type 0: Not a Combination Pro | JUCI | | | | | | |
| | | | | | | | | | |
| Marketing Information | | | | | | | | | |
| Marketing Category | Applicatio | on Number or Monograph Cit | ation | Marketing Sta | rt Date | Marketi | ng End Date | | |
| unapproved drug other | | | | 07/01/2018 | | | | | |
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Labeler - ELMEDITEC CO.,LTD (694771074)

Registrant - ELMEDITEC CO.,LTD (694771074)

| Establishment | | | | | | | | | |
|-------------------|---------|-----------|------------------------|--|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | | |
| ELMEDITEC CO.,LTD | | 694771074 | manufacture(72440-020) | | | | | | |

Revised: 7/2018

ELMEDITEC CO.,LTD