DENTI WHOO BLUE TABLETGARGLE- sodium fluoride tablet SUN LIFE SCIENCE 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.

Sodium Fluoride

Sodium Bicarbonate

Tartaric Acid

Hydroxypropylcellulose

Hydroxypropyl methylcellulose

Silica

Zea Mays (Corn) Starch

Sodium Cocoyl Glutamate

Maltitol

Mannitol

Erythritol

Potassium Acesulfame

Magnessium Stearate

Brilliant Blue

Menthol

Yucca Vera Leaf/Root Extract

fragrance

Tooth-decay prevention, Odor removal from the mouth and Oral Cleansing

Keep out of reach of children

USAGE: Put 1 tablet in the mouth and use the tongue and lips to rub the gums, teeth, and tongue, gargle it with water, and rinse it several times

- 1) Observe the specified usage capacity.
- 2) Store in a cool place with no sunlight and less moisture.
- 3) Avoid swallowing.
- 4) This product contains 583 ppm of fluorine.
- 5) This product contains fluorine, so if you swallow a large amount, consult a doctor or dentist

immediately.

6) When used by children under the age of 6, use under the supervision of their guardians to

avoid swallowing.

7) Keep out of reach of children under the age of 6

For dental use only



DENTI WHOO BLUE TABLETGARGLE

sodium fluoride tablet

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:86157-0006 |
| Route of Administration | DENTAL | | |

| Active Ingredient/Active Moiety | | | |
|--|----------------------|-----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 1.10037 g | |

| Inactive Ingredients | | |
|----------------------------------|----------|--|
| Ingredient Name | Strength | |
| TARTARIC ACID (UNII: W4888I119H) | | |
| MALTITOL (UNII: D65DG142WK) | | |

| SODIUM BICARBONATE | (UNII: 8MDF5V39QO) |
|--------------------|--------------------|
|--------------------|--------------------|

| Product Characteristics | | | |
|-------------------------|---------|--------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 15mm |
| Flavor | MENTHOL | Imprint Code | none |
| Contains | | | |

| Packaging | | | |
|---------------------------|---|-------------------------|-----------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:86157-0006-1 | 8 in 1 PACKAGE; Type 0: Not a Combination Product | 04/06/2022 | |

| Marketing Information | | | |
|---|---------------------------------|---|--|
| Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| | 04/06/2022 | | |
| | Application Number or Monograph | Application Number or Monograph Marketing Start Citation Date | |

Labeler - SUN LIFE SCIENCE CO LTD (695149648)

Registrant - SUN LIFE SCIENCE CO LTD (695149648)

| Establishment | | | | |
|-------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| SUN LIFE SCIENCE CO LTD | | 695149648 | manufacture(86157-0006) | |

Revised: 4/2022 SUN LIFE SCIENCE CO LTD