

ZOOBY TURTLE MELON- sodium fluoride aerosol, foam
Young Dental Manufacturing Co 1, LLC

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.

Description

Product Name- ZOOBY, 1.23 % APF Foam (Turtle Melon Flavor)

Distributed By - Denticator Earth City, MO 63045.

Net Weight - 4.4 OZ (125g)

RX Only

ZOOBY, 1.23 % APF Foam (Turtle Melon Flavor) contains 1.23 % Fluoride Ion from 2.72 % Sodium Fluoride. Does not contain chlorofluorocarbon propellant. Gluten free.

Indications

For the topical application of fluoride to aid in the protection against dental caries. Optimized low pH for a 1 minute fluoride treatments.

Dosage and Administration

1. Break protective tab adjacent to trigger.
2. Shake can thoroughly for at least 15 seconds before each use.
3. Hold can completely upside down to dispense and fill fluoride tray by slowly depressing the nozzle. (The foam will expand slightly higher than the fluoride tray.)
4. Dry tooth surfaces prior to inserting tray(s) in mouth.
5. Insert tray(s) into patient's mouth and have them bite down for 1-4 minutes.
6. Remove tray(s) and have patient expectorate.
7. Advise the patient not to eat, drink or rinse for 30 minutes after the treatment.

Warnings

Do not spray toward open flame. Contents under pressure. Do not puncture or incinerate. Keep out of reach of children. Store between 59-86° F (15-30° C). Keep from freezing.

Refer to Material Safety Data Sheet for additional information. For emergencies contact

Route of Administration DENTAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | SODIUM FLUORIDE | 2.72 g in 100 g |

Product Characteristics

| | | | |
|----------|------------|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | WATERMELON | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0273-0394-44 | 125 g in 1 CAN; Type 0: Not a Combination Product | 08/01/2010 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 08/01/2010 | |

Labeler - Young Dental Manufacturing Co 1, LLC (006309355)

Revised: 1/2023

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