

ZOOBY GROWLIN GRRRAPE- 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 (Growlin Grrrape Flavor)

Distributed By - Denticator Earth City, MO 63045.

Net Weight - 4.4 OZ (125g)

RX Only

ZOOBY, 1.23 % APF Foam (Growlin Grrrape Flavor) contains 1.23 % Fluoride Ion from 2.72 % Sodium Fluoride. The Product is free from 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 INFOTRAC at 1-800-535-5053

Product Label

Product Label of 1.23 % APF Foam (Growlin Grrrape)

BLEED

TRIM LINE

SIDE PANEL

NDC 0273-0358-44 INEL

INDICATIONS: DAPK DICIPI AV DAMEI For the topical application of fluoride to aid in the protection against dental caries. Optimized low pH for a 1 minute fluoride treatment.

CONTAINS: Sodium Fluoride in a proprietary acidulated phosphate flavored foam base. 1.23% Fluoride Ion from 2.72% Sodium Fluoride. Sweetened with sucralose and xylitol. Does not contain chlorofluorocarbon propellant. Gluten free.

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.

WARNING:
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 INFOTRAC at 1-800-535-5053.

CAUTION:
Shake well before each use. Rx only

distributed by
Denticator
Earth City, MO 63045
www.denticator.com
(800)227-3321

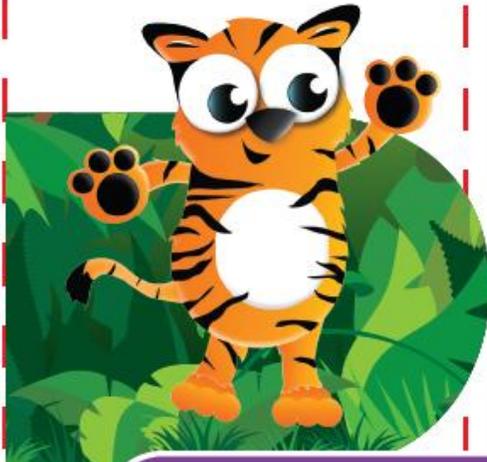
Made in USA

To dispense:
Before first use, gently lift upward on nozzle to break protective shipping tab located adjacent to trigger.

1. Shake well
2. Invert can completely
3. Depress nozzle slowly



SAFE PRINT AREA



ZOOPY

1.23% APF Foam

Growlin' Grrrape™

Gluten Free
1.23% Fluoride Ion
APF Topical Fluoride Foam
(acidulated phosphate fluoride)
NET WT. 4.4 OZ (125g)

REORDER NO. 612001

© 2010 Denticator International

SAFE PRINT AREA



+D6456120011/\$0273035844N

12002969A Rev 08/2011

654055

ZOOPY GROWLIN GRRRAPE

sodium fluoride aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0273-0358
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-0358-44	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

Young Dental Manufacturing Co 1, LLC