ZOOBY CHOCOLATE CHOW- 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 (Chocolate Chow Flavor)

Distributed By - Denticator Earth City, MO 63045.

Net Weight - 4.4 OZ (125mg)

R_X Only

ZOOBY, 1.23 % APF Foam (Chocolate Chow 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 INFOTRAC at 1-800-535-5053

Product Label

Product Label of 1.23 % APF Foam (Chocolate Chow)



ZOOBY CHOCOLATE CHOW

sodium fluoride aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0273- 0392
Route of Administration	DENTAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium Fluoride (Fluoride Ion)	Fluoride Ion	2.72 g in 100 g	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHOCOLATE	Imprint Code		
Contains				

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0273-0392-44	125 g in 1 CAN		

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: 9/2011 Young Dental Manufacturing Co 1, LLC