EMMI-DENT WHITENING- sodium fluoride paste, dentifrice
EMAG AG

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Emmi®-dent Whitening

Drug Facts

Active Ingredient

Sodium Fluoride 0.32% (0.19% w/v fluoride ion)

Purpose

Anticavity toothpaste

Use

helps protect against cavities

Warning

Keep out of reach of children under 6 yrs. of age.

If more than used for dental cleaning is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

* adults and children 2 yrs. & older: clean teeth thoroughly after meals or at least twice a day or use as directed by a dentist
* do not swallow
* to minimize swallowing use a pea-sized amount in children unter 6
* supervise children's dental cleaning until good habits are established
* children under 2 yrs.: ask a dentist

Inactive ingredients

sorbitol, water, hydrated silica, sodium bicarbonate, propylene glycol, pentasodium triphosphate, C-14-16 olefin sulfonate, celluose gum, aroma/fragrance, titanium dioxide, sodium saccharin, zinc chloride

Questions?

1-833-682-8902

Distributed by Ultra Oral Care Inc.,
Spring, Texas, 77386

PRINCIPAL DISPLAY PANEL - 75 mL Tube Carton

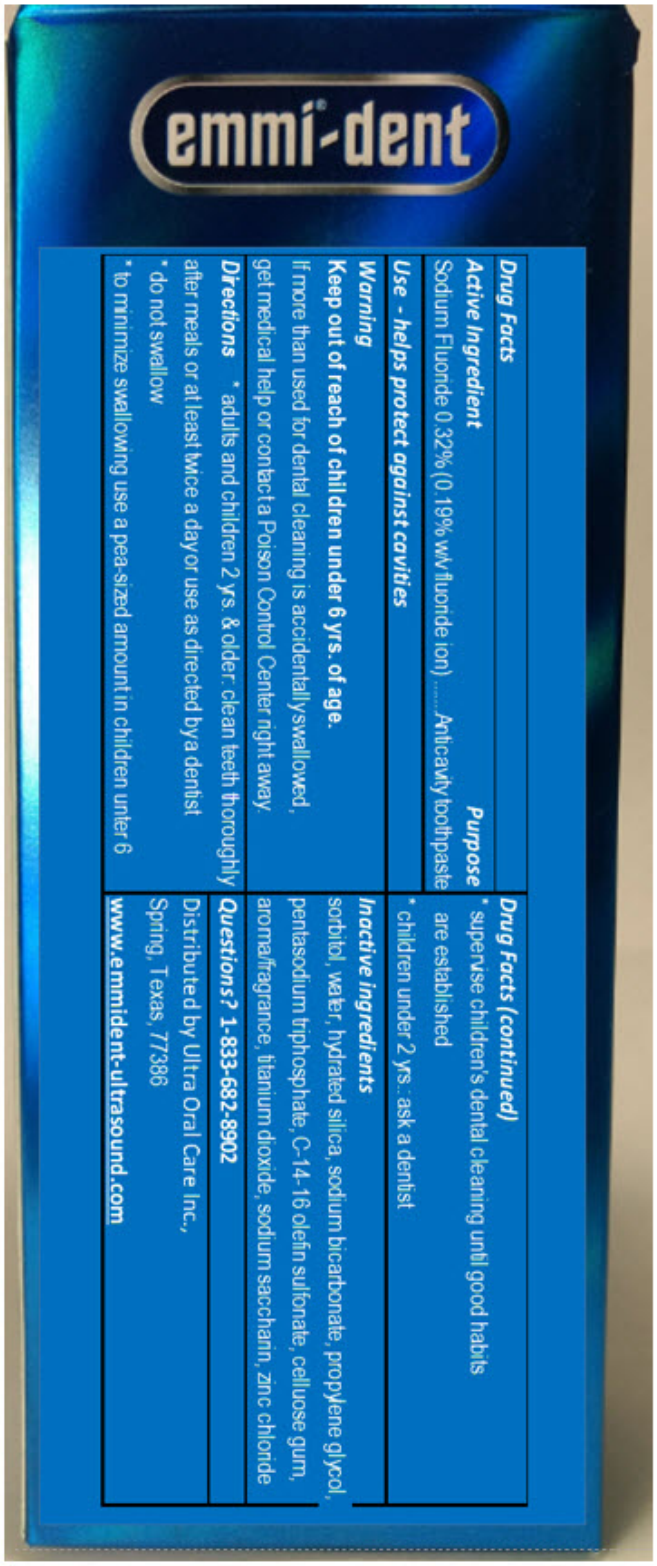
emmi®-dent

Ultrasound Toothpaste

Whitening

Made in Germany

Ideal für
100% Ultraschall®
Made by Emag Germany



EMMI-DENT WHITENING

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63956-003

Route of Administration	DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	Sodium Fluoride	320 mg in 75 mL

Inactive Ingredients

Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Sodium Bicarbonate (UNII: 8MDF5V39QO)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Tripolyphosphate Anhydrous (UNII: 9SW4PFD2FZ)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Zinc Chloride (UNII: 86Q357L16B)	

Product Characteristics

Color	WHITE, BLUE (White and Blue stripes)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63956-003-03	1 in 1 CARTON	07/30/2019	
1		75 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	07/30/2019	

Labeler - EMAG AG (343617614)

Establishment

Name	Address	ID/FEI	Business Operations
Durodont GmbH		341254136	MANUFACTURE(63956-003)

Revised: 1/2023

EMAG AG