

**EMMI-DENT KIDS- 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 Kids

Drug Facts

Active Ingredient

Sodium Fluoride 0.11% (0.06% 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 under 6
- * supervise children's dental cleaning until good habits are established
- * children under 2 yrs.: ask a dentist

Inactive ingredients

water, sorbitol, hydrated silica, propylene glycol, sodium C-14-16 olefin sulfonate, cellulose gum, aroma/fragrance, titanium dioxide, sodium methylparaben, sodium saccharin

Questions?

1-833-682-8902

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

www.emmident-ultrasound.com

PRINCIPAL DISPLAY PANEL - 75 mL Tube

emmi[®]-dent

Emmi-dent Kids

Ultrasound Toothpaste

for
Kids

Made in Germany

Made by Emag Germany



EMMI-DENT KIDS

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63956-002
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
Sodium Fluoride (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU4080)		Sodium Fluoride	110 mg in 75 mL	
Inactive Ingredients				
Ingredient Name			Strength	
Water (UNII: 059QF0K00R)				
Sorbitol (UNII: 506T60A25R)				
Hydrated Silica (UNII: Y6O7T4G8P9)				
Propylene Glycol (UNII: 6DC9Q167V3)				
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)				
Titanium Dioxide (UNII: 15FIX9V2JP)				
Methylparaben Sodium (UNII: CR6K9C2NHK)				
Saccharin Sodium (UNII: SB8ZUX40TY)				
Product Characteristics				
Color	WHITE (white homogeneous mass)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63956-002-02	75 mL in 1 TUBE; Type 0: Not a Combination Product	07/15/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part355	07/15/2019		

Labeler - EMAG AG (343617614)

Establishment

Name	Address	ID/FEI	Business Operations
Durodont GmbH		341254136	MANUFACTURE(63956-002)

Revised: 1/2023

EMAG AG