

**EMMI-DENT FRESH- 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 Fresh

Drug Facts

Active Ingredient

Sodium Fluoride 0.199% (0.11% 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, tetrapotassium pyrophosphate, xanthan gum, sodium C-14-16 olefin sulfonate, aroma, mentha arvensis leaf oil, titanium dioxide, sodium methyl paraben, sodium saccharin, allantoin, chamomilla recutita (matricaria) flower extract, salvia triloba leaf extract

Questions?

1-833-682-8902

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

www.emmident-ultrasound.com

PRINCIPAL DISPLAY PANEL - 75 ml Tube Carton

emmi®-dent

PROFESSIONAL

100% ULTRASOUND

CLEANS GENTLY WITHOUT BRUSHING

emmi®-dent

Ultrasound toothpaste

fresh

Made in Germany

<p>DE VORBEUGEND: KARIES ZAHNFLEISCHPROBLEME ZAHNVERFÄRBUNGEN PLAQUE ZAHNSTEIN SCHLECHER ATEM</p> <p>EN PREVENTIVE AGAINST: CARIES GUM PROBLEMS TOOTH DISCOLOURATION PLAQUE TARTAR BAD BREATH</p> <p>FR PRÉVENTION CONTRE: CARIES SAIGNEMENT DES GENCIVES DÉCOLORATION DES DENTS PLAQUE DENTAIRE TARTRE MAUVAISE HALEINE</p> <p>ES PREVENCIÓN CONTRA: CARIES PROBLEMAS DE ENCIAS DECOLORACIÓN DE DIENTES PLACA SARRO MAL ALIENTO</p> <p>IT AIUTA A PREVENIRE: CARIE GENGIVITE DECOLORAZIONE DENTALE PLACCA DENTARIA TARTARO ALITOSI</p>	 <p>emmi-dent PROFESSIONAL 100% ULTRASOUND CLEANS GENTLY WITHOUT BRUSHING emmi-dent Ultraschall Zahncreme Ultrasound toothpaste Dentifrice pour ultrasons Crema dental ultrasonido Dentifricio agli ultrasuoni fresh Made in Germany</p>	<p>Ideal für Emmi-dent Ultraschall-Zahnbürsten</p>  <p>Emmi Ultrasonic GmbH Gerauer Straße 34 64546 Morfelden-Walldorf Deutschland Tel: 06105/ 40 67 20 www.emmi-ultrasonic.de info@emmi-ultrasonic.de</p> <p>PZN 5960130 e 75 ml</p> <p> 9M V3  4 040513 650053</p>
<p>Drug Facts Active Ingredient Sodium Fluoride 0.199% (0.11 w/v Fluoride Ion) Anticarioly toothpaste</p> <p>Use • helps protect against cavities</p> <p>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 Poison Control Center right away.</p> <p>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</p>	<p>Drug Facts (continued) • supervise children's dental cleaning until good habits are established • children under 2 yrs.: ask a dentist</p> <p>Inactive Ingredients te traposasi um pyrophosphate, xanthan gum, sodium C-14-16 olefin, sulfonate, aroma, mentha arvensis leaf oil, allantoin, chamomilla re cutita flower extract, saliva trilobal leaf extract, sodium saccharin, sodium methyl paraben, CI 77891</p> <p>Questions? 1-833-682-8902 Distributed by Ultra Oral Care Inc., Spring, Texas, 77386 www.emmident-ultrasound.com</p>	

EMMI-DENT FRESH

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63956-004
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	199 mg in 75 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Propylene Glycol (UNII: 6DC9Q167V3)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
Xanthan Gum (UNII: TTV12P4NEE)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	
Mentha Arvensis Leaf oil (UNII: 1AEY1M553N)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
Allantoin (UNII: 344S277G0Z)	
CHAMOMILE (UNII: FGL3685T2X)	
THREE-LOBE SAGE (UNII: 3V97D33N0K)	

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:63956-004-01	1 in 1 CARTON	07/15/2019	
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	07/15/2019	

Labeler - EMAG AG (343617614)

Establishment

Name	Address	ID/FEI	Business Operations
Durodont GmbH		341254136	MANUFACTURE(63956-004)

Revised: 1/2023

EMAG AG