

**EMMI-DENT FRESH- sodium fluoride paste, dentifrice  
EMAG AG**

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**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](http://www.emmident-ultrasound.com)**

**PRINCIPAL DISPLAY PANEL - 75 ml Tube Carton**

emmi® DENT

FRESH  
PROFESSIONAL

emmi® DENT

100% ULTRASOUND

Ultrasound Toothpaste

Made in Germany

Ideal

100% Ultraschall®

Made by EMAG Germany



emmi DENT	
<b>Drug Facts</b>	<b>Drug Facts (continued)</b>
<b>Active Ingredient</b> Sodium Fluoride - less than 0.1%	<b>Purpose</b> Anticavity toothpaste
<b>Use</b> helps protect against cavities	<b>Inert Ingredients</b> agua, sorbitol, hydrated silica, propylene glycol, tetrapotassium pyrophosphate, xanthan gum, sodium C-14-16 olefin sulfonate, aroma, mentha, anensis leaf oil, sodium methylparaben, sodium saccharin, allantoin, chamomilla recutita flower extract, salvia triloba leaf extract, menthol, C177891
<b>Warnings</b> <b>Keep out of reach of children under 6 yrs. of age.</b> If more than used for dental cleaning is accidentally swallowed get medical help or contact Poison Control Center right away.	<b>Questions?</b> 1-561-463-6120 Distributed by D&P Sales Services Group, LLC, Florida, 33332 <a href="http://www.emmident-ultrasound.com">www.emmident-ultrasound.com</a> <a href="mailto:CustomerService@emmident-ultrasound.com">CustomerService@emmident-ultrasound.com</a>
<b>Directions</b> * 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	

## EMMI-DENT FRESH

sodium fluoride paste, dentifrice

### Product Information

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Sodium Fluoride</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	199 mg in 75 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Hydrated Silica</b> (UNII: Y6O7T4G8P9)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>Xanthan Gum</b> (UNII: TTV12P4NEE)	
<b>Sodium C14-16 Olefin Sulfonate</b> (UNII: O9W3D3YF5U)	
<b>Mentha Arvensis Leaf oil</b> (UNII: 1AEY1M553N)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
<b>METHYLPARABEN SODIUM</b> (UNII: CR6K9C2NHK)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>Allantoin</b> (UNII: 344S277G0Z)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>THREE-LOBE SAGE</b> (UNII: 3V97D33N0K)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	

### Product Characteristics

<b>Color</b>	WHITE (white homogeneous mass)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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 DRUG	M021	07/15/2019	

**Labeler** - EMAG AG (343617614)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Weckerle Cosmetics		341251644	MANUFACTURE(63956-004)

Revised: 12/2024

EMAG AG