

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

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**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 under 6
- \* supervise children's dental cleaning until good habits are established
- \* children under 2 yrs.: ask a dentist

**Inactive ingredients**

Agua, hydrated silica, hydrogenated starch hydrolysate, propylene glycol, penta sodium triphosphate, tetra potassium pyrophosphate, sodium C14-16 olefin sulfonate, dicalcium phosphate dihydrate, disodium pyrophosphate, silica, cellulose gum, aroma, sodium saccharin, zinc lactate citric acid, sodium sulfate, sodium chloride, benzyl alcohol, CI 42051

**Questions?**

**1-833-682-8902**

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

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

emmi® DENT

WHITENING

emmi® DENT

100% Ultrasound

Ultrasound Toothpaste

Made in Germany

Ideal

100% Ultraschall®

Made by EMAG Germany



<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active Ingredient</b> Sodium Fluoride 0.32% (0.19% w/v fluoride ion).....	<b>Purpose</b> Anticavity toothpaste	* supervise children's dental cleaning until good habits are established * children under 2 yrs.: ask a dentist	
<b>Use</b> helps protect against cavities		<b>Inactive ingredients</b> agua, hydrated silica, hydrogenated starch hydrolysate, propylene glycol, pentasodium triphosphate, tetrapotassium pyrophosphate, sodium C14-16 olefin sulfonate, dicalcium phosphate dihydrate, disodium pyrophosphate, silica, cellulose gum, aroma, sodium saccharin, zinc lactate citric acid, sodium sulfate, sodium chloride, benzyl alcohol, CI 42051	
<b>Warning</b> 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.		<b>Questions? 1-561-463-6120</b> 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 WHITENING

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63956-003
<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)	Sodium Fluoride	320 mg in 75 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0K00R)	
<b>Hydrated Silica</b> (UNII: Y6O7T4G8P9)	
<b>Hydrogenated Starch Hydrolysate</b> (UNII: 27F77DSJ5V)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Sodium Tripolyphosphate Anhydrous</b> (UNII: 9SW4PFD2FZ)	
<b>POTASSIUM PYROPHOSPHATE</b> (UNII: B9W4019H5G)	
<b>Sodium C14-16 Olefin Sulfonate</b> (UNII: O9W3D3YF5U)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>SODIUM ACID PYROPHOSPHATE</b> (UNII: H5WD9LZUD)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>Cellulose Gum</b> (UNII: K679OBS311)	
<b>Saccharin Sodium</b> (UNII: SB8ZUX40TY)	
<b>Zinc Lactate</b> (UNII: 2GXR25858Y)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>Sodium Sulfate</b> (UNII: 0YPR65R21J)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)	
<b>PATENT BLUE V</b> (UNII: 8QE473DV1Z)	

### Product Characteristics

<b>Color</b>	WHITE, BLUE (White and Blue stripes)	<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:63956-003-03	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 Drug	M021	07/30/2019	

**Labeler** - EMAG AG (343617614)

## Establishment

Name	Address	ID/FEI	Business Operations
Weckerle Cosmetics		341251644	MANUFACTURE(63956-003)

Revised: 12/2024

EMAG AG