

**EMMI DENT SODIUM FLUORIDE ANTICAVITY MILD- 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 Sodium Fluoride Anticavity Toothpaste

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Active Ingredient

Sodium fluoride 0.243% (0.16 w/v fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities.

Warnings

Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.
- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing).
- Supervise children as necessary until capable of using without supervision.
- Children under 2 years: Consult a dentist or doctor.

Inactive Ingredients

water, hydrated silica, sorbitol, propylene glycol, tetrapotassium pyrophosphate, xanthan, gum, sodium C14-16 olefin sulfonate, flavor, titanium dioxide, sodium methylparaben, sodium saccharin, allantoin, limonene, chamomile (chamomilla recutita) flower extract, three-lobe sage (salvia triloba) leaf extract, citral

Representative Labeling



SUPERIOR DENTAL HYGIENE

Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.243% (0.16% w/v fluoride ion)	Anticavity

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Questions? 1-866-766-0278 ext. 105 (M-F 8:00 am - 5:00 pm PST)

Distributed by:

Emmi-Tech Inc.
7500 West Lake Mead Blvd., Ste 302
Las Vegas, Nevada 89128, USA

Made in Germany

sales@emmi-dent.com
www.emmi-dent.com



Specially formulated anti-cavity toothpaste for use with Emmi-dent (Emmi-dent 6 not included in this box):



Emmi-dent 6



emmi-dent

SUPERIOR DENTAL HYGIENE



Emmi-dent Brush Heads are available in different sizes and colors. For optimum cleansing performance, replace the head every 3 months (brush heads not included in this box):



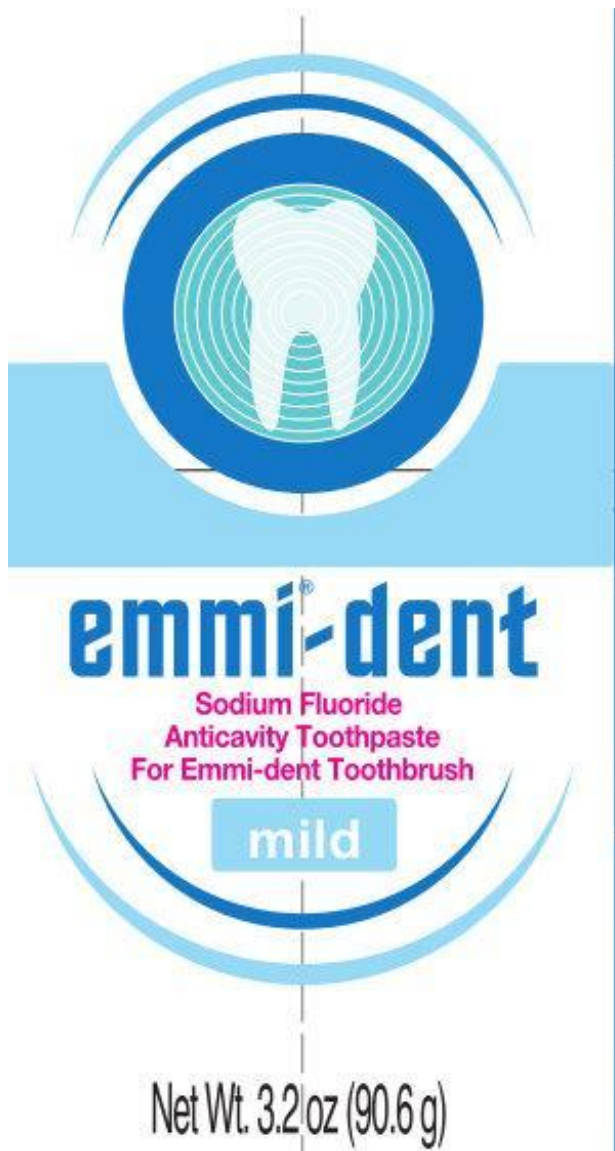
Adults:
E2, E4



Ladies & Children:
K2, K4

emmi-dent

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PZN 9491057

9 M

best before: see tube seam

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EMMI DENT SODIUM FLUORIDE ANTICAVITY MILD			
sodium fluoride paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63956-001
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.16 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
HYDRATED SILICA (UNII: Y6O7T4G8P9)			

SORBITOL (UNII: 506T60A25R)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)
XANTHAN GUM (UNII: TTV12P4NEE)
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
ALLANTOIN (UNII: 344S277G0Z)
LIMONEN-10-OL, (+)- (UNII: 1Q8KVB0R3J)
CHAMOMILE (UNII: FGL3685T2X)
THREE-LOBE SAGE (UNII: 3V97D33N0K)
CITRAL (UNII: T7EU0O9VPP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63956-001-90	1 in 1 PACKAGE		
1		90.6 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/22/2014	

Labeler - EMAG AG (343617614)

Registrant - EMAG AG (343617614)

Establishment

Name	Address	ID/FEI	Business Operations
EMAG AG		343617614	manufacture(63956-001)