

**EUROFRESH WHITENING- sodium fluoride paste, dentifrice**  
**Farmasi US LLC**

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**Eurofresh Whitening Toothpaste**

***DRUG FACTS***

***ACTIVE INGREDIENTS***

Sodium Fluoride - 0.24%

***PURPOSE***

Anticavity

***USE***

Helps protect against cavities

Helps whiten teeth

***WARNINGS***

**Do not use**

if irritation occurs and persists.

**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.

***DIRECTION***

- Supervise children as necessary until capable of using without supervision.
- Do not swallow.
- Rinse away toothpaste residue thoroughly after brushing.
- Adults and children 2 years and older: brush teeth thoroughly after meals or at least twice a day, or use as directed by a dentist or physician.
- Children under 6 years: instruct in good brushing and rinsing habits (to minimize swallowing).
- Children under 2 years: ask a dentist or physician.

***INACTIVE INGREDIENTS***

Calcium Carbonate, Sorbitol, Water/Aqua, Hydrated Silica, Lauryl Glucoside, Xanthan Gum, Flavour/Aroma, Titanium Dioxide, Sodium Benzoate, Sodium Saccharin, Tea Tree

Oil/Melaleuca alternifolia Leaf Oil, Panax Ginseng Root Extract, aloe Juice Barbadosis Leaf juice, Salvadora Persica Bark/Root Extract.

**Questions or Comments?**

info@farmasius.com **1786 236 7338**

Monday - Friday (9 a.m-6 p.m. EST)

**Package Labeling:**





**Eurofresh Whitening toothpaste**

112 g e3.95 oz.

**Eurofresh Whitening toothpaste**

Aloe Vera + Tea Tree + Ginseng + Miswak + Carbonate

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**Manufactured by:** Tan-Alize Kozmetik ve Temizlik Ürünleri San. ve Tic. A.Ş., Ömerli Mah. Üran Cad. No: 32 / 34797 Çekmeköy / İSTANBUL - Made in TURKEY **EU Responsible Person:** Farmasi Central Europe S.R.O. Stará Vajnorská 147/17, 831 04, Bratislava, Slovenská Republika. **Distributed By:** FARMASI US LLC, 2315 NW 107 TH AVE, STE 1B 12, DORAL, FL 33172.

GMP ISO 9001 HACCP

**farmasi.com**

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## EUROFRESH WHITENING

sodium fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74690-008
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.08 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>SALVADORA PERSICA ROOT</b> (UNII: 526M7ZU616)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74690-008-01	1 in 1 BOX	12/01/2020	
1		112 g 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	12/01/2020	

**Labeler** - Farmasi US LLC (113303351)

Revised: 11/2023

Farmasi US LLC