

FARMASI WHITENING- sodium fluoride paste, dentifrice
Farmasi US LLC

Farmasi Whitening Toothpaste

DRUG FACTS

ACTIVE INGREDIENTS

Sodium Fluoride 0.24 % (0.15% w/v fluoride ion)

PURPOSE

Anticavity

USES

Helps protect teeth and prevents cavities. Whitens teeth by removing surface stains.

WARNINGS

Keep out of reach of children

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

DIRECTIONS

Adults and children 6 years of age and older: brush teeth thoroughly after meals of at least twice a day, or as directed by 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/Aloe Barbadensis Leaf Juice, Salvadora Persica Bark/Root Extract.

Questions or Comments?

info@farmasius.com Monday - Friday (9 a.m - 6 p.m. EST) **1 786 238 7338**

25g Package Labeling:



FARMASI

FARMASI

Whitening
toothpaste
Pasta de Dientes

Whitening
toothpaste
Pasta de Dientes



25g e 0.9 oz.

25g e 0.9 oz.

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(9 am – 6 pm EST)

Manufactured by/Manufacturado por: Tan-Alize Kozmetik ve Temizlik Ürünleri San. ve Tic. A.Ş. Ömerli Mah. Uran Cad. No: 32 / 34797 Çekmeköy / İSTANBUL
Made in TURKEY. EU Responsible Person / Responsable de la UE: Farmasi Central Europe S.R.O. Grösslingová 62, 811 09 Bratislava, Slovenská Republika.
Importado por: FAR COSMETICS MEXICO FCM2010146Y8. Miguel de Cervantes Saavedra No. 25, Piso 3, Oficina 303, Col. Granada, Alcaldía Miguel Hidalgo, Ciudad de México, 11520

ISO 9001 Quality Management System



Información del Medicamento
INGREDIENTE ACTIVO **PROPÓSITO**
Fluoruro de Sodio - 0.24 %
(0.15% p/v de iones de fluoruro).....Anticaries

USOS
Ayuda a proteger los dientes y previene las caries. Blanquea los dientes eliminando las manchas superficiales.

ADVERTENCIAS
Mantenga el producto fuera del alcance de los niños menores de 6 años, si se ingiere accidentalmente más de lo que se usó para cepillar, busque ayuda médica o comuníquese con el centro de intoxicaciones de inmediato.

DIRECCIONES
Adultos y niños a partir de los 6 años de edad: cepílese bien los dientes después de las comidas o al menos dos veces al día o según las indicaciones de un dentista o médico.

INGREDIENTES INACTIVOS
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/Aloe Barbadensis Leaf Juice, Salvadora Persica Bark/Root Extract.

¿PREGUNTAS O COMENTARIOS?
info@farmasius.com
1 786 238 7338
Lunes-Viernes
(9 am - 6 pm EST)

Distributed by / Distribuido por: - Farmasi US LLC 2315 NW 107 TH AVE, STE 1B 12, DORAL, FL 33172 - FARMASI COSMETICS RO S.R.L Bucuresti Sectorul 1, Calea FLOREASCA, Nr. 246c, Etaj 18. Romania. - FORTUNA COSMETICS MEXICO, S DE RL DE CV FCM201014J22 Blvd. Miguel de Cervantes Saavedra No. 25, Piso 3, Oficina 303, Col. Granada, Alcaldía Miguel Hidalgo, Ciudad de México, 11520. -FARMASI COSMETICS CANADA INC. GOWLING WLG (CANADA) LLP Suite 2300, Bentall 5, 550 Burrard Street Vancouver, British Columbia, V6C 2B5.

25g e 0.9 oz.
FARMASI farmasi.com

8690131120351

2000798

01-2020



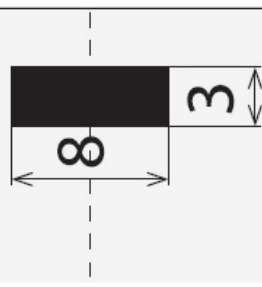
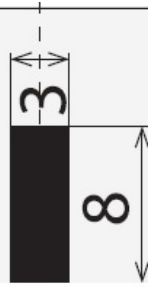
FARMASI

Whitening
toothpaste



25g e 0.9 oz.





DRUG FACTS

Active Ingredient
Sodium fluoride 0.24% (0.15% w/v fluoride ion).....Anticavity

USES Helps protect teeth and prevents cavities. Whitens teeth by removing surface stains.

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 6 years of age and older: brush teeth thoroughly after meals or at least twice a day, or as directed by 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/Aloe Barbadensis Leaf Juice, Salvadora Persica Bark/Root Extract.

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Manufactured by: Tan-Alize Kozmetik ve Temizlik Ürünleri San. ve Tic. A.Ş. Ömerli Mah. Uran Cad. No: 32 / 34797 Çekmeköy / İSTANBUL Made in TURKEY **EU Responsible Person:** Farmasi Central Europe S.R.O. Grösslingová 62, 811 09 Bratislava, Slovenská Republika. **Distributed by:** Farmasi US LLC 2315 NW 107TH AVE, STE 1B 12, DORAL, FL 33172



8690131120351 4000494


FARMASI

Whitening
toothpaste



25g e 0.9 oz.

112g Package Labeling:

DRUG FACTS**ACTIVE INGREDIENT**

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(0.15% w/v fluoride ion).....Anticavity

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Whitens teeth by removing surface
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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/Aloe
Barbadensis Leaf Juice, Salvadora
Persica Bark/Root Extract.

Questions or Comments?

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Ömerli Mah. Uran 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.

**FARMASI****Whitening**
toothpaste

112g e 3.95 oz.



farmasi.com

4000174

112g e 3.95 oz.

<p>Drug Facts</p> <p>ACTIVE INGREDIENT PURPOSE Sodium fluoride 0.24% (0.15% w/v fluoride ion).....Anticaries</p> <p>USES Helps protect teeth and prevents cavities. Whitens teeth by removing surface stains.</p> <p>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.</p> <p>DIRECTIONS Adults and children 6 years of age and older: brush teeth thoroughly after meals or at least twice a day, or as directed by a dentist or physician.</p> <p>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/Aloe Barbadensis Leaf Juice, Salvadora Persica Bark/Root Extract.</p> <p>Questions or Comments? info@farmasius.com 1 786 238 7328 Monday - Friday (9 am - 6 pm EST)</p> <p><i>Manufactured by:</i> Tan-Alize Kozmetik ve Temizlik Ürünleri San. ve Tic. A.Ş. Ömerli Mah. Uran Cad. No: 32 / 34797 Çekmeköy / İSTANBUL Made In TURKEY <i>EU Responsible Person:</i> Farmasi Central Europe S.R.O. Stará Vajnorská 147/17, 831 04 Bratislava, Slovenská Republika. <i>Distributed by:</i> FARMASI US LLC 2315 NW 107 TH AVE, STE 1B 12, DORAL, FL 33172.</p>	<p style="font-size: 2em; font-weight: bold;">FARMASI</p> <p style="font-size: 3em; font-weight: bold;">Whitening toothpaste</p> 	<p>Información del Medicamento</p> <p>INGREDIENTE ACTIVO PROPÓSITO Fluoruro de Sodio - 0.24 % (0.15% p/v de iones de fluoruro)...Anticaries</p> <p>USOS Ayuda a proteger los dientes y previene las caries. Blanquea los dientes eliminando las manchas superficiales.</p> <p>ADVERTENCIAS Mantenga el producto fuera del alcance de los niños menores de 6 años, si se ingiere accidentalmente más de lo que se usó para cepillar, busque ayuda médica o comuníquese con el centro de Intoxicaciones de inmediato.</p> <p>DIRECCIONES Adultos y niños a partir de los 6 años de edad cepílese bien los dientes después de las comidas o al menos dos veces al día o según las indicaciones de un dentista o médico.</p> <p>INGREDIENTES INACTIVOS 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/Aloe Barbadensis Leaf Juice, Salvadora Persica Bark/Root Extract.</p> <p>¿PREGUNTAS O COMENTARIOS? info@farmasius.com 1 786 238 7328 Lunes-Viernes (9 am - 6 pm EST)</p> <p><i>Fabricado por:</i> Tan-Alize Kozmetik ve Temizlik Ürünleri San. ve Tic. A.Ş. Ömerli Mah. Uran Cad. No: 32 / 34797 Çekmeköy / İSTANBUL Hecho en Turquía <i>Persona responsable de la UE:</i> Farmasi Central Europe S.R.O. Stará Vajnorská 147/17, 831 04 Bratislava, Slovenská Republika. <i>Distribuido por:</i> FARMASI US LLC 2315 NW 107 TH AVE, STE 1B 12, DORAL, FL 33172.</p>	<p style="font-size: 2em; font-weight: bold;">FARMASI</p> <p style="font-size: 3em; font-weight: bold;">Whitening toothpaste</p> 
<p>2000287</p>  <p>8 690131 118921</p>	<p>112g e 3.95oz.</p>	<p>112g e 3.95oz.</p> <p>FARMASI farmasi.com</p> 	<p>112g e 3.95oz.</p>

FARMASI WHITENING			
sodium fluoride paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74690-012
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
TEA TREE OIL (UNII: VIF565UC2G)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SALVADORA PERSICA ROOT (UNII: 526M7ZU616)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74690-012-01	1 in 1 BOX	04/15/2021	
1		112 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:74690-012-02	1 in 1 BOX	09/25/2021	
2		25 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	04/15/2021	

Labeler - Farmasi US LLC (113303351)

Revised: 11/2023

Farmasi US LLC