

ALEGRIA- sodium monofluorophosphate paste, dentifrice
Seowangmo corporation

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.

ACTIVE INGREDIENT

Active Ingredient: Sodium Monofluorophosphate 0.76%

INACTIVE INGREDIENT

Inactive Ingredients: D-Sorbitol Solution, Silicon Dioxide, Dentaltype silica, Polyethylene Glycol 1500, Glycerin, Sodium Lauryl Sulfate, Carboxymethylcellulose Sodium, Sodium Benzoate, Allantoinie Chlorohydroxy Aluminum, Aminocaproic Acid, Xylitol, Saccharin Sodium Hydrate, Licorice Extract, Sophora Extract, Aloevera Gel, Peppermint Oil, L-Menthol, Anethole, Carvone, Mica, Silver foil, Purified Water

PURPOSE

Purpose: Anticavity

WARNINGS

Warnings: If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children: Keep out of reach of children under 6 years of age.

Use

Use: Aids in the prevention of dental cavities

Directions

Directions: 1) Adults and children 2 years of age and older: Brush teeth thoroughly preferably after each meal or at least twice a day or as directed by a dentist or doctor. 2) Children under 6 years: To minimize swallowing, use a pea-sized amount and supervise brushing until good habits are established. 3) Children under 2 years: Consult a dentist or doctor.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



ALEGRIA

의약외품

SEOWANGMO

ALEGRIA[®]

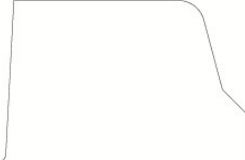
TOOTHPASTE



Alegria toothpaste is a high functional toothpaste which contains pure—silver of 99% and bio element. It prevents dental periodontal diseases, gingival diseases and dental calculus so that it keeps your teeth always healthy and clean, causing fresh feeling always.



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ALEGRIA



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알레그리아치약

고기능성치약

알레그리아치약은 순도 99%의 순은성분과 약용성분 함유로 잇몸질환 및 치주질환의 문제를 해결한 치약으로 구취제거를 하여 치아를 튼튼하고 건강하게 만들어 주므로 늘 상쾌한 기분을 느낄수 있습니다.

[주성분] 아산화규소, 덴탈티립실리카, 입복 소인산나트륨, 알란토인블로로히드록시알 루미늄, 아미노카프로산

[용법용량] 적당량을 칫솔에 묻혀 칫솔질에 의해 치아를 닦는다.

[효능효과] 이를 희게 유지하고 튼튼하게 한다. 구강 내를 청결히 유지한다. 구강내를 상쾌하게 한다. 충치예방·구취를 제거한다. 심미 효과를 높인다. 치은염·치주염(치조농루)의 예방, 치주질환예방, 잇몸질환의 예방, 치태제거(안티프라그)

[사용상 주의사항]
1) 이 치약의 불소 함유량은 1,000 ppm임
2) 만 6세 이하의 어린이가 사용할 경우, 1회당 원두콩 크기 정도의 소량의 치약을 사용하고, 빨아 먹거나, 삼키지 않도록 보호자의 지도하에 사용할 것
3) 만 6세 이하의 어린이가 많은 양을 삼켰을 경우, 즉시 의사 또는 치과의사와 상의할 것
4) 만 6세 이하의 어린이의 손에 닿지 않는 곳에 보관할 것

[제품명] 알레그리아치약
[중량] 130g
[제조번호 및 사용기한] 별도표기
[보관방법 및 사용기간]
기밀용기, 실온(1~30℃)에 보관
제조일로부터 36개월
[기술지도 및 판매원] (주)서왕모
대구광역시 수성구 청수로 24길 41
[제조원] (주)네오메디칼
경기도 안성시 왕곡면 천덕산로 683
[소비자상담실] 1670-4528
www.alegria.kr
Made in Korea

Drug Facts Active Ingredients: Sodium Hexafluoroantimonate 0.179%(0.15% w/w fluoride ion).....Antibway	Purpose Aids in the prevention of dental cavities	Drug Facts (continued) Directions Alegria toothpaste is for children 2 years of age 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 they capable of using without supervision. Children under 2 years of age, Consult a dentist or doctor.
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.	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.	Inactive Ingredients: 100% Glyceryl Acrylate, Ammonium Lauryl Sulfate, Polyethylene Glycol 1500, Glycerin, Ammonium Hydroxide, Sodium Lauryl Sulfate, Potassium Peroxydisulfate, Sodium Bicarbonate, Sodium Fluoride, Silver Foil, Calcium Hydroxyapatite, Titanium Dioxide, Silicon Dioxide, Silver Foil, Aloe Extract, Mica, Avocado, L-Carvone, L-Menthol, Flavor

KFDA
식품의약품안전처 허가
본 제품에 인공적으로 첨가된 인공 착색료는 없습니다.
제조업체명 기입을 위하여 표본에 포함되어 있습니다.

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ALEGRIA

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70406-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.98 g in 130 g

Inactive Ingredients

Ingredient Name	Strength
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Glycerin (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70406-010-01	130 g in 1 CARTON; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/02/2016	

Labeler - Seowangmo corporation (689605288)

Registrant - Seowangmo corporation (689605288)

Establishment

Name	Address	ID/FEI	Business Operations
Seowangmo corporation		689605288	manufacture(70406-010)

Revised: 2/2016

Seowangmo corporation