

GO SMILE LUXURY AM- sodium monofluorophosphate paste, dentifrice
Go Smile, Inc.

GOSMILE (as PLD) - LUXURY TOOTHPASTE, AM (44873-106)

ACTIVE INGREDIENTS

SODIUM MONOFLUOROPHOSPHATE 0.76% (0.13% w/v FLUORIDE ION)

PURPOSE

ANTICAVITY

USES

AIDS IN THE PREVENTION OF DENTAL CAVITIES.

WARNINGS

KEEP OUT OF REACH OF CHILDREN UNDER 6 YEARS OLD.

DIRECTIONS

- ADULTS AND CHILDREN 2 YEARS OF AGE AND OLDER: BRUSH TEETH THOROUGHLY FOR TWO MINUTES AT LEAST TWICE A DAY PREFERABLY AFTER EACH MEAL OR AS DIRECTED BY A DOCTOR OR DENTIST. THIS PRODUCT SHOULD BE USED AS PART OF AN ORAL HEALTH PROGRAM THAT INCLUDES REGULAR FLOSSING AND DENTAL CHECK-UPS.
- 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 TWO YEARS OF AGE: CONSULT A DENTIST OR A DOCTOR.

INACTIVE INGREDIENTS

SORBITOL, PURIFIED WATER, HYDRATED SILICA, GLYCERIN, SODIUM LAURYL SULFATE, FLAVOR, CELLULOSE GUM, TITANIUM DIOXIDE, SODIUM SACCHARIN, SODIUM BENZOATE.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE.

IF MORE THAN USED FOR BRUSHING IS ACCIDENTALLY SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

DRUG FACTS
Active Ingredients: Sodium Monofluorophosphate 0.76% (0.13% w/v fluoride ion)
Purpose: Anticavity
Uses: 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: <ul style="list-style-type: none"> • Adults and children 2 years of age and older: Brush teeth thoroughly for 2 minutes at least twice a day preferably after each meal or as directed by a dentist or doctor. This product should be used as part of an oral health program that includes regular flossing and dental check-ups. • 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 of age: Consult a dentist or a doctor.
Other Information: Store at room temperature.
Inactive Ingredients: Sorbitol, purified water, hydrated silica, glycerin, sodium lauryl sulfate, flavor, cellulose gum, titanium dioxide, sodium saccharin, sodium benzoate

PHARMACOLOGIE
Ingrédient Actif: Monofluorophosphate de Sodium à 0.76%, (Teneur en ions fluorure 0.13% w/v)
Utilité: Anti-caries
Usage: Aide à prévenir contre les caries.
Avertissements: Tenir hors de portée des enfants de moins de 6 ans. En cas d'ingestion accidentelle d'une quantité supérieure à celle nécessaire au brossage des dents, consulter immédiatement un médecin ou appeler un centre antipoison.
Mode d'emploi: <ul style="list-style-type: none"> • Adultes et enfants de plus de 2 ans: Brosser les dents pendant au moins deux minutes deux fois par jour de préférence après les repas, ou selon les recommandations de votre médecin. Ce produit devrait faire partie d'un programme d'hygiène bucco-dentaire qui inclut l'utilisation de fil dentaire et des visites régulières auprès de votre dentiste. • Apprendre aux enfants de moins de 6 ans de bien brosser et rincer leurs dents (pour avaler le moins de produit). Surveiller les enfants autant que nécessaire jusqu'à ce qu'ils maîtrisent correctement le brossage des dents. • Enfants de moins de 2 ans: Consulter un dentiste ou médecin.
Autres informations: Conserver à température ambiante.
Ingrédients Inactifs: Sorbitol, eau, silice hydratée, glycérine, laurylsulfate de sodium, arôme, carboxyméthylcellulose, dioxyde de titane, saccharinate de sodium, benzoate de sodium.

WWW.GO SMILE.COM, 1-877-8-SMILES, GO SMILE, Inc. Berkeley, CA 94710.
 Made in the USA/Fabriqué aux États-Unis. Imported by/Importateur
 MMP Enterprises Ltd. 130 Industry Street, Unit 33, Toronto, ON M6M 5G3.
 NPN 80035870

GO SMILE®
 LUXURY TOOTHPASTE
 DENTIFRICE DE LUXE



KEEP YOUR SMILE WHITE

NET WT. 3.5 OZ. 100 G

GO SMILE LUXURY AM
 sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44873-106
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C8107560) (FLUORIDE ION)		0.13%

SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.15 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
SORBITOL (UNII: 506T60A25R)				
WATER (UNII: 059QF0KO0R)				
HYDRATED SILICA (UNII: Y607T4G8P9)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44873-106-13	100 g in 1 TUBE; Type 0: Not a Combination Product	10/27/2015	
2	NDC:44873-106-11	28 g in 1 TUBE; Type 0: Not a Combination Product	10/27/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M021	10/27/2015		

Labeler - Go Smile, Inc. (139729631)

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Go Smile, Inc.