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

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GOSMILE (as PLD) - TOOTHPASTE, RELAX (44873-007)

# **PURPOSE**

**ANTICAVITY** 

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, VALERIAN OFFICINALIS RHIZOME/ROOT EXTRACT.

#### **PURPOSE**

ANTICAVITY

#### **ACTIVE INGREDIENTS**

SODIUM MONOFLUOROPHOSPHATE 0.76% (0.13% W/V FLUORINE ION)

#### **WARNINGS**

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 fluorine ion)

Purpose: Anticavity

Uses: Aids in the prevention of dental cavities.

Warnings: Keep out of reach of children under 6 years of ago. 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 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 byears of age in good brushing and rinsing habits it o 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, valeriana officinalis rhizome/root extract.

# **PHARMACOLOGIE**

Ingrédient Actif: Monofluorophosphate de Sodium à 0.76%, (Teneur en ions fluorure:0.13% w/v)

Utilité: Anti-carie

Usage: Aide à prévenir contres 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:

- 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 réquières 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.

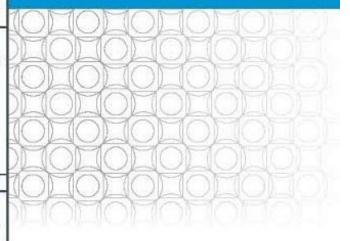
Ingrédients Inactifs: Sorbitol, eau, silice hydrarée, glycérine, laurylsulfate de sodium, arôme, carboxyméthylcellulose, dioxyde de titane, saccharinate de sodium, benzoate de sodium, extrait de racine de valériane.

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# KEEP YOUR SMILE WHITE



NET WT. 1.0 OZ. 28 G

#### DRUG FACTS

Active Ingredients: Sodium Monofluorophosphate 0.76% (0.13% w/v fluorine 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

- 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, punified water, hydrated silica, glycerin, sodium lauryl sulfate, flavor, cellulose gum, titanium dioxide, sodium saccharin, sodium benzoate, valeriana officinalis rhizome/root extract.

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Ingrédient Actif: Monofluorophosphate de Sodium à 0.76%, (Teneur en ions fluorure:0.13% W/v)

Utilité: Anti-carie

Usage: Aide à prévenir contres 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 appeter un centre antipoison.

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- Enfants de moins de 2 ans: Consulter un dentiste ou médecin.

Autres Informations: Conserver à température ambiante.

Ingrédients Inactifs: Sorbitol, eau, silice hydratée, glycérine, lauryisulfate de sodium, arôme, carboxyméthylcellulose, dioxyde de titane, saccharinate de sodium, benzoate de sodium, extrait de racine de valériane.

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# **KEEP YOUR SMILE WHITE**

NET WT. 3.5 OZ. 100 G

# **GO SMILE RELAX**

sodium monofluorophosphate paste, dentifrice

Product Type HUMAN OTC DRUG Item Code (Source) NDC:44873-007

Route of Administration ORAL

### **Active Ingredient/Active Moiety**

Active ingredient/Active Plotety			
Ingredient Name	Basis of Strength	Strength	
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ 56Q) (FLUORIDE ION -	ELLIODIDE ION	0.76 g	

UNII:Q80VPU408O)	FLUURIDE IUN	in 100 g
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Inactive Ingredients		
Ingredient Name	Strength	
SORBITOL (UNII: 506T60A25R)		
WATER (UNII: 059QF0KO0R)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
GLYCERIN (UNII: PDC6A3C0OX)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
VALERIAN (UNII: JWF5YAW3QW)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
<b>1</b> NDC:44873-007	100 g in 1 TUBE; Type 0: Not a Combination Product	05/05/2011		
2 NDC:44873-007	28 g in 1 TUBE; Type 0: Not a Combination Product	05/05/2011		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	05/05/2011	

# **Labeler -** Go Smile, Inc. (139729631)

Revised: 11/2023 Go Smile, Inc.