

SMARTH EXTRA STRENGTH WHITENING- sodium monofluorophosphate paste, dentifrice
Carib Sales, LLC

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.

Smarth™
Extra Strength Whitening

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion)

Purpose

AntiCavity Toothpaste

Use

aids in the prevention of dental cavities

Warning

Keep out of the 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 immediately

Directions

- Do not swallow
- Supervise children as necessary until capable of using without supervision
- Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing)
- Adults and children 6 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
- Children under 6 years of age: Do not use unless directed by a doctor or dentist

Inactive Ingredients

Calcium Carbonate, Sorbitol, Demineralized Water, Tetra Sodium Ortho Phosphate, Tetra Sodium Pyro Phosphate, Sodium Lauryl Sulphate, Hydrated Silica, Sod. CMC, Flavor, Sodium Silicate, Sodium Benzoate, Sodium Saccharin

PRINCIPAL DISPLAY PANEL - 181g Tube Carton

SMARTH™

Extra Strength Whitening Fluoride Toothpaste

Extra
WHITENING

NET WT 6.4 Oz [181g]

SMARTH™

Extra Strength Whitening Fluoride Toothpaste
 Dentífrico blanqueador al flúor extra fuerte
 Dentifrice blanchissant au fluor extra fort

Extra
WHITENING

Extra
BLANQUEADOR

Extra
BLANCHER

NET WT 6.4 Oz [181g]

✓ Fluoride Protection • Long Lasting Freshness • New Whitening Formula

✓ Protección de flúor • Frescura duradera • Nueva fórmula blanqueadora

✓ Protection fluor • Fraîcheur longue durée • Nouvelle formule blanchissante

NEW
NOUVEAU
NUEVO

SMARTH™

Extra Strength Whitening Fluoride Toothpaste
 Dentífrico blanqueador al flúor extra fuerte
 Dentifrice blanchissant au fluor extra fort

Extra
WHITENING

Extra
BLANQUEADOR

Extra
BLANCHER

NET WT 6.4 Oz [181g]



Lot no.:
 Mfg. Date:
 Exp. Date:



- All day freshness
- Deep cleaning action
- All day confidence
- Aliento fresco duradero
- Acción limpiadora profunda
- Confianza que dura el día entero
- Halcine fraîche longue durée
- Nettoie en profondeur
- Confiance en soi tout au long de la journée



Free



Manufactured For/Fabriqued por/Fabrikado por: CARIB SALES, LLC 4500 NW 135TH STREET OPA LOCKA, FL 33054, USA, Made in India/Hecho en la India/Fabriqué en Inde. Code No.: GUJ/GC/565

Information sur le produit:

Fonction
 Substances actives: monofluorophosphate de sodium - 0,76% (0,1% PV en fluor) — Dentifrice anti-caries
 Utilisation : contribue à la prévention des caries dentaires

Avertissement:
 Tenir hors de la portée des enfants de moins de 6 ans. Si une quantité plus importante que celle utilisée pour le brossage est avalée accidentellement, demandez immédiatement une assistance médicale ou contactez un centre anti-poison.

Mode d'utilisation
 • Ne pas avaler • Surveiller les enfants aussi longtemps que nécessaire jusqu'à ce qu'ils soient capables d'utiliser le produit sans surveillance • Apprendre aux enfants de moins de 12 ans à bien se brosser les dents et à se rincer la bouche correctement (sans de manière les langues d'ingestion) • Pour les adultes et les enfants de 6 ans et plus: brosser les dents soigneusement, de préférence après chaque repas ou au moins deux fois par jour, ou comme recommandé par votre dentiste ou médecin • Pour les enfants de moins de 6 ans: ne pas utiliser sans l'indication d'un médecin ou dentiste

Autres Composants:
 Carbonate de calcium, cobalt, eau déminéralisée, hydroxyéthylphosphate de sodium, pyrophosphate de sodium, butylparabène de sodium, silice hydratée, oxyde d'hydroxytoluène sodique, ammoniac, stéarate de sodium, benzoate de sodium, saccharine de sodium

Información del producto:

Función
 Ingredientes activos: Monofluoroborato de sodio - 0,76% (0,1% PV en de fluor) — Dentifrice anti-caries
 Uso: contribuye a la prevención de las caries

Advertencia:
 Mantenga a alajado del alcance de niños menores de seis años de edad. En caso de ingerir una cantidad mayor de la necesaria para el cepillado de los dientes, buscar asistencia médica o contactar un centro toxicológico.

Modo de uso
 • No ingerir • Supervisar a los niños hasta que aprendan a usar el producto correctamente • Enseñar el cepillado y enjuague correcto a menores de doce años (para reducir el riesgo de ingestión) • Adultos y menores de seis años de edad: cepillar bien los dientes, preferiblemente después de cada comida o al menos dos veces al día, o bajo indicación profesional (de un médico o dentista) • Menores de seis años de edad: usar solamente bajo indicación profesional

Excipientes:
 Carbonato de calcio, cobalto, agua desmineralizada, hidroxifosfato de sodio, silice hidratada, carbonato de sodio, eesodato, silicato de sodio, benzoato sódico, sacarina sódica

Drug Facts

Active Ingredient
 Sodium monofluorophosphate 0.76% (0.1% w/w fluoride ion) — Anticavity Toothpaste

Purpose
 Use: aids in the prevention of dental caries

Warning:
 Keep out of the 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 immediately.

Directions
 • Do not swallow • Supervise children as necessary until capable of using without supervision • Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing) • Adults and children 6 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 • Children under 6 years of age: Do not use unless directed by a dentist or doctor

Inactive ingredients
 Calcium Carbonate, Cobalt, Demineralized Water, Beta Sodium Citrate Phosphate, Beta Sodium Pyro Phosphate, Sodium Lauryl Sulfate, Hydrated Silica, Soda Citrate, Sodium Fluoride, Sodium Stearate, Sodium Benzoate, Sodium Saccharin





SMARTH EXTRA STRENGTH WHITENING

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60927-118
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium monofluorophosphate (UNII: C810JCZ56Q) (Fluoride ion - UNII:Q80VPU408O)	Fluoride ion	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Calcium Carbonate (UNII: H0G9379FGK)	
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0K00R)	
Sodium Pyrophosphate (UNII: O352864B8Z)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
Sodium Silicate (UNII: IJF18F77L3)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Saccharin Sodium (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60927-118-13	1 in 1 CARTON		
1		18.1 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/01/2013	

Labeler - Carib Sales, LLC (081234528)**Registrant** - Vikshara Trading & Investment Ltd (675920690)**Establishment**

Name	Address	ID/FEI	Business Operations
Vikshara Trading & Investment Ltd		675920690	MANUFACTURE(60927-118)