

SMARTH EXTRA STRENGTH REGULAR- 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 Fluoride Toothpaste REGULAR

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, Sodium Lauryl Sulphate, Hydrated Silica, Sod. CMC, Flavor, Sodium Silicate, Sodium Benzoate, Sodium Saccharin

PRINCIPAL DISPLAY PANEL - 181g Tube Carton

SMARTH™

Extra Strength Fluoride Toothpaste

REGULAR

NET WT 6.4 Oz [181g]

SMARTH™

Extra Strength Fluoride Toothpaste
 Dentífrico al flúor extra fuerte
 Dentífrice au fluor extra fort

REGULAR
 CLASICO
 CLASSIQUE

NET WT 6.4 Oz [181g]

- ✓ Fluoride Protection • Long Lasting Freshness • Great Clean Sensation
- ✓ Protección de flúor • Frescura duradera • Gran sensación de limpieza
- ✓ Protection fluor • Fraîcheur longue durée • Sensation de propreté

NEW
 NOUVEAU
 NUEVO

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Extra Strength Fluoride Toothpaste
 Dentífrico al flúor extra fuerte
 Dentífrice au fluor extra fort

REGULAR
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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
- Haleine fraîche longue durée
- Nettoie en profondeur
- Confiance en soi tout au long de la journée

Manufactured For/Fabrique pour: CARIB SALES, LLC 4500 NW 135TH STREET OPA LOCKA, FL 33054, USA, Made in India/Hecho en la India/Fabrique en Inde. Code No.: GUJ/GC/555

Información sur le produit:

Fonction: Substance active: Monofluorophosphate de sodium - 0.76% (0.1% PV en fluorure) — Dentifrice anti-carie

Attention: contribue à la prévention des caries dentaires

Avvertimento: Tenir hors de la portée des enfants de moins de 6 ans. Si une quantité plus importante que celle u libéré pour le brossage est avalée accidentellement, demander immédiatement une assistance médicale ou contacter un centre antipoison.

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 (à la fin de brossage les rincer abondamment) • 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 surveillance sur indication d'un médecin ou dentiste

Autres Composants: Carbonate de calcium, sodocitrate, eau déminéralisée, butylène glycol, saccharine, carboxyméthylcellulose sodique, arôme, stéarate de sodium, benzoate de sodium, hydroxyéthylcellulose, saccharine

Información del producto:

Ingrediente activo: Monofluoroborato de sodio - 0.76% (0.1% w/v en fluor) — Dentifrico anti-carie

Función: Uso: contribuye a la prevención de las caries

Advertencia: Mantenga alejado 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 ingesta • Adultos y menores de seis años de edad: cepillar bien las 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, Sorbitol, agua desmineralizada, hidroxietilcelulosa, hidroxipropilcelulosa, hidroxietilcelulosa, carbonato de sodio, eodocitrate, sodocitrate de sodio, benzoato sódico, sacarina sódica

Drug Facts:

Active ingredient: Sodium monofluorophosphate 0.76% (0.1% w/v fluoride ion) — Anti-Cavity 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 with thorough, 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, Sodium Lauryl Sulphate, Hydroxyethyl Cellulose, Sodium Starch Glycolate, Sodium Benzoate, Sodium Saccharin



SMARTH EXTRA STRENGTH REGULAR

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60927-117
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: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM SILICATE (UNII: JF18F77L3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60927-117-12	1 in 1 CARTON		
1		181 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(60927-117)