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

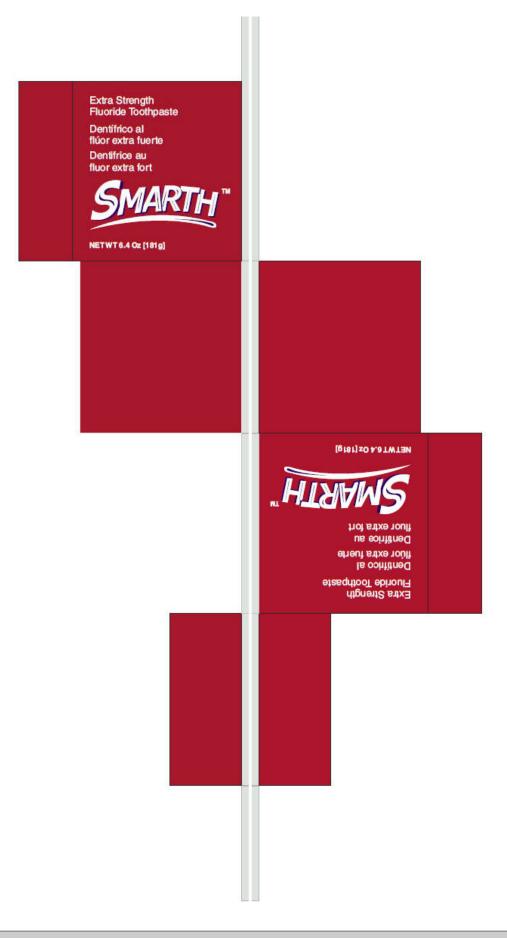
SMARTHTM

Extra Strength Fluoride Toothpaste

REGULAR

NET WT 6.4 Oz [181g]





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sodium monofluorophosphate paste, dentifrice

Product Information	1							
Product Type	HUMAN OTC DRU	JG	Ite m Cod	de (Source)		NDC:60927-117		
Route of Administration	n DENTAL							
Active Ingredient/A	ctive Moiety							
	Ingredient Name					Basis of Strength Streng		
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)					FLUORI	de ion	7.6 mg in 1 g	
Inactive Ingredients	3							
Ingredient Name						Strength		
CALCIUM CARBONATE	. ,							
SORBITOL (UNII: 506T6	0A25R)							
WATER (UNII: 059QF0KC	0 R)							
SODIUM LAURYL SULFA	ATE (UNII: 368GB5141J)							
HYDRATED SILICA (UNI	:Y6O7T4G8P9)							
SODIUM SILICATE (UNII	: IJF18F77L3)							
SODIUM BENZOATE (UN	NII: OJ245FE5EU)							
SACCHARIN SODIUM (U	NII: SB8ZUX40TY)							
Packaging								
# Item Code	Package Description	n Ma	rketing S	Start Date	Ma	arketing	End Date	
1 NDC:60927-117-12	1 in 1 CARTON							
1	181 g in 1 TUBE							
Marketing Infor	mation							
Marketing Infor Marketing Category	mation Application Number or N	Ionograph C	itation	Marketing St	art Date	Market	ing End Dat	

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)

Revised: 10/2013