

**UPC 801803 00211 MEGAFRESH GEL FLUORIDE TOOTH- sodium fluoride paste, dentifrice
American Amenities, Inc.**

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.

Active Ingredient: Sodium Fluoride (0.243%)

Purpose: Anticavity

Uses: Aids in the prevention of dental cavities

If more than used for brushing is accidentally swallowed, get medical help or contact a poison control center immediately.

Keep out of reach of children under six years of age

Adults and children of two 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 a doctor. Instruct children under six years of age in good brushing and rinsing habit (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: consult a dentist or doctor.

Sorbitol, Hydrated Silica, Glycerin, Purified Water, Polyethylene Glycol, Sodium Lauryl Sulfate, Carboxymethylcellulose Sodium, Flavor, Xanthan Gum, Saccharin Sodium, Methylisothiazolinone

Mega Fresh™

gel fluoride toothpaste

NET WT 6.6 oz (187 g)

Model: NG-TP-260

UPC: 801803 00211

Drug Facts		Drug Facts (continued)
Active Ingredient Sodium Fluoride (0.247%) (0.5% w/w fluoride ion)	Purpose Anticavity	Directions Adequate for children 2 years of age and older. Brush teeth thoroughly, preferably after each meal or snack with water, or use clean cloth or gauze. Instruct children under 6 years of age in good brushing and flossing habits. Do not use as a substitute for regular dental care. See your dentist for more information on proper brushing and flossing techniques. Consult your dentist for more information.
Uses Aids in the prevention of dental caries.		Inactive Ingredients Sorbitol, Hydroxyethyl Cellulose, Polyethylene Glycol, Sodium Lauryl Sulfate, Calcium Hydroxide, Sodium Fluoride, Xanthan Gum, Saccharin Sodium, Methylparaben.
Warnings Keep out of reach of children under 6 years of age. Fluoride may irritate if swallowed. If accidentally swallowed, get medical help or contact a Poison Control Center right away.		
Manufactured for American Dental, Inc. Miami, FL 33133 Made in China.		

UPC 801803 00211 MEGAFRESH GEL FLUORIDE TOOTH

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54157-109
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54157-109-01	17 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
2	NDC:54157-109-02	24 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
3	NDC:54157-109-03	43 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
4	NDC:54157-109-04	78 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
5	NDC:54157-109-05	85 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
6	NDC:54157-109-06	130 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
7	NDC:54157-109-07	181 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
8	NDC:54157-109-08	200 g in 1 TUBE; Type 0: Not a Combination Product	06/03/2017	
9	NDC:54157-109-09	4.25 g in 1 POUCH; Type 0: Not a Combination Product	06/03/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/03/2017	

Labeler - American Amenities, Inc. (181454026)

