MEGAFRESH- sodium fluoride gel, 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 (0.22%)

Purpose: Anticavity

Uses: Aids in the prevention of dental cavities

For external use only. Keep out of reach of children

Keep out of reach of children under six years of age

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

Adults and children of two years of age and older: Brush teeth thoroughly, perferrably 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 swollowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: consult a dentist or doctor.

Purified Water,Sorbitol, Polyethylene Glycol 1500, Carboxymethylcellulose Sodium, Sodium Lauryl Sulfate, Flavour, Carbomer Homopolymer Type C, Hydrated Silica, Saccharin Sodium,Methylparaben, Propylparaben

Mega Fresh™
gel fluoride toothpaste
Net Wt. 7 oz (200 g)

Reorder NO.TP-700C

Drug Facts	Drug Facts (continued)
Active Ingredient — Purpose Sodium Fluoride – 0.22% (0.1% w/v fluoride ion) — Anticavity	Directions Adults and children 2 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. 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 doctor.
Uses Aids in the prevention of dental cavities.	Inactive Ingredients Purified Water, Sorbitol, Polyethylene Glycol 1500, Carboxymethylcellulose Sodium, Sodium Lauryl Sulfate, Flavour, Carbomer Homopolymer Type C, Hydrated Silica, Saccharin Sodium, Methylparaben, Propylparaben.
Warning 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.	

Manufactured for American Amenities, Inc.
Woodinville, WA 98072
Made in China.

MEGAFRESH
sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54157-102
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)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54157-102-01	17 g in 1 TUBE		
2	NDC:54157-102-02	24 g in 1 TUBE		
3	NDC:54157-102-03	35 g in 1 TUBE		
4	NDC:54157-102-04	43 g in 1 TUBE		
5	NDC:54157-102-05	50 g in 1 TUBE		
6	NDC:54157-102-06	70 g in 1 TUBE		
7	NDC:54157-102-07	78 g in 1 TUBE		
8	NDC:54157-102-08	90 g in 1 TUBE		
9	NDC:54157-102-09	100 g in 1 TUBE		
10	NDC:54157-102-10	120 g in 1 TUBE		
11	NDC:54157-102-11	130 g in 1 TUBE		
12	NDC:54157-102-12	150 g in 1 TUBE		
13	NDC:54157-102-13	181 g in 1 TUBE		
14	NDC:54157-102-14	200 g in 1 TUBE		
15	NDC:54157-102-15	4.25 g in 1 POUCH		
16	NDC:54157-102-16	3 g in 1 POUCH		
17	NDC:54157-102-17	5 g in 1 POUCH		
18	NDC:54157-102-18	10 g in 1 POUCH		
19	NDC:54157-102-19	71 g in 1 TUBE		
20	NDC:54157-102-20	85 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/04/2013	

Labeler - American Amenities, Inc. (181454026)

Registrant - American Amenities, Inc. (181454026)

Revised: 1/2015 American Amenities, Inc.