

**DAWNMIST - toothbrush, toothpaste and floss kit paste
Donovan Industries, 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.

DawnMist Toothbrush, Toothpaste and Floss Kit

DRUG FACTS

Active Ingredient: SMFP 0.76% Purpose: Anticavity

Use: Aids in the prevention of dental cavities

Warning: Keep out of reach of children under 6 years of age.

If you accidentally swallow more than used for brushing seek professional assistance or contact a Poison Control Center Immediately.

Directions : Adults and children 2 yrs. and older. Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician.

Children under 6 yrs.: To minimize swallowing use a pea sized amount and supervise brushing until good habits are established.

Children Under 2 years: Ask a dentist or physician.

Sorbitol, Silica, Water, Sodium Lauryl Sulfate,
Xanthan Gum, Sodium Benzoate, Titanium Dioxide,
Peppermint Oil, Sodium Saccharin

Expiration Date: Expiration Date and Batch No. on Primary Package

Manufactured for:

Donovan Industries, Inc.

Tampa, FL 33626-3061

www.dawnmist.com

1-800-334-4404

MADE IN MALAYSIA

DawnMist

Cavity Fighting



Formula

Mint Flavor

Toothbrush, Toothpaste and Floss Kit

100 Kits Each Net Wt .1 OZ 3g

CONTAINS ONE TOOTHBRUSH, ONE TUBE
OF TOOTHPASTE AND ONE FLOSS

<p>DRUG FACTS</p> <p>Active Ingredient: SMPF 0.75%</p> <p>Uses: Aids in the prevention of dental carities.</p> <p>Warnings: Keep out of reach of children under 3 years of age. If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.</p>	<p>Purpose: Anticavity</p> <p>Directions: Adults and children 2 yrs. and older: Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist or physician.</p> <p>Children under 2 yrs.: To minimize swallowing use a pea sized amount and supervise brushing.</p> <p>Children under 2 years: Ask a dentist or physician.</p>
	
<h2 style="text-align: center;">Toothbrush, Toothpaste & Floss Kit</h2> <p style="text-align: center;">100 Kits (Each Net Wt. 1 OZ. (3g))</p> <p style="text-align: center;">CONTAINS ONE TOOTHBRUSH, ONE TUBE OF TOOTHPASTE AND ONE FLOSS</p> <p style="text-align: center;">Reorder No. TPKIT</p>	
<p>Inactive Ingredients: Sodium Lauryl Sulfate, Sodium Bicarbonate, Sodium Benzoate, Titanium Dioxide, Peppermint Oil, Sodium Saccharin.</p> <p>Expiration Date: Expiration Date & Batch No. on Primary Package.</p>	<p>Manufactured for: Dawn Dental Products, Inc. Tampa, FL 33626-3161 www.dawnmint.com 1-800-534-4404 MADE IN MALAYSIA</p>
 <p>7 57709 00932 1</p> <p>Rev. No. 09/08/14788</p>	

NOT FOR RESALE

TOOTH CARE KIT



Compliments of SunMeadow • Thanks for all you do!

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TOOTH CARE KIT



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TOOTH CARE KIT



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DRUG FACTS
 Important information about this product.
 Read the Drug Facts label every time you use the product.
 Keep this information with the product.
 If you accidentally swallow more than used for brushing seek professional assistance or contact a Poison Control Center immediately.
 Do not use if you are allergic to any of the ingredients. Each toothbrush is thoroughly sterilized and ready to use. Do not use if the brush is damaged or if the bristles are frayed.
 Use: Aids in the prevention of dental cavities.
 Children under 6 years: To minimize swallowing use a pea sized amount and supervise brushing until good habits are established.
 Children Under 2 years: Ask a dentist or physician.
 Warning: Keep out of reach of children under 6 years of age.
 If you accidentally swallow more than used for brushing seek professional assistance or contact a Poison Control Center immediately.



Toothbrush, Toothpaste & Floss Kit

100 Kits [Each Net Wt. 1 OZ. (30g)]

CONTAINS ONE TOOTHBRUSH, ONE TUBE OF TOOTHPASTE AND ONE FLOSS

Reorder No. TPKIT



Rev. No. 09/08/14188

Manufactured for:
 Dorenen Industries, Inc.
 Tampa, FL 33626-3061
 Phone: 813-988-1000
 1-800-334-4404
 MADE IN MALAYSIA

Inactive Ingredients:
 Sorbitol, Silica, Water, Sodium Lauryl Sulfate,
 Xanthan Gum, Sodium Benzoate, Titanium Dioxide,
 Peppermint Oil, Sodium Saccharin.
Expiration Date: Expiration Date & Batch No. on Primary Package

DAWNMIST
 toothbrush, toothpaste and floss kit paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55504-0540
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	0.76 g in 3 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SACCHARIN (UNII: FST467XS7D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55504-0540-1	2.83 g in 1 KIT		
2	NDC:55504-0540-2	2.83 g in 1 KIT		
3	NDC:55504-0540-3	3 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/01/2009	

Labeler - Donovan Industries, Inc. (096662267)**Registrant** - Fulijaya Manufacturing SDN. BHD. (652087115)**Establishment**

Name	Address	ID/FEI	Business Operations
Fulijaya Manufacturing SDN. BHD.		652087115	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
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Donovan Industries, Inc.		096662267	import
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Revised: 8/2009

Donovan Industries, Inc.