ORALLINE SECURE- sodium fluoride paste, dentifrice ORALLINE- sodium fluoride gel, dentifrice J.M. Murray Center 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 0.24% w/w (0.15% w/v Fluoride Ion)

Inactive Ingredients

Sorbitol, Hydrated Silica, DI Water, Glycerin, PEG 12, Sodium Lauryl Sulfate, Cellulose Gum, Titanium Dioxide, Sodium Saccharin, FD C Blue 1

Purpose

Anticavity Toothpaste

Use

Use - Helps protect against cavities

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.

Children under 6 years of age. Use a pea-sized amount and instruct in good brushing and rinsing habits to reduce swallowing. Supervise children as necessary until capable of using without supervision.

Warnings

If you accidentally swallow more than used for brushing get medical help or contact a poison control center immediately.

Keep Out of Reach of Children

Children under 2 years of age consult a doctor or a dentist

Keep out of the reach of children under 6 years of age.

Product Labels

OraLine Fluoride Toothpaste ADA accepted. The ADA Council on Scientific Affairs Acceptance of OraLine Fluoride Mint Toothpaste is based on finding that the product is effective in helping to prevent and reduce tooth decay when used as directed

No animal based ingredients. Mint Flavor Net Wt 3 oz (85 g)



No animal based ingredients. Mint Flavor

Net Wt.3 oz. (85g)

UORIDE TOOTHPASTE

The ADA Council on Scientific Affairs' Acceptance of OraLine Fluoride Mint Toothpaste is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed.

- Council on Scientific Affairs, American Dental Association

Drug Facts

Active Ingredient

Sodium Fluoride 0.24% w/w (0.15% w/v Fluoride Ion)

Purpose Anticavity toothpaste

Use Helps protect against cavities

Warnings

Keep out of the reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

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. ■ Children under 6 years of age: use a pea-sized amount and instruct in good brushing and rinsing habits to reduce swallowing. Supervise children as necessary until capable of using without supervision.

Children under 2 years of age: Consult a dentist or doctor.

Inactive Ingredients: Sorbitol, Hydrated Silica, DI Water, Glycerin, PEG 12, Sodium Lauryl Sulfate, Cellulose Gum, Titanium Dioxide, Flavor, Sodium Benzoate, Disodium Phosphate, Sodium Saccharin, FD&C Blue #1.

No animal based ingredients. Mint Flavor



CLEAR FLUORIDE TOOTHPASTE

The ADA Council on Scientific Affairs' Acceptance of OraLine Secure Clear Fluoride Mint Toothpaste is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed.

- Council on Scientific Affairs, American Dental Association

Drug Facts

Active Ingredient

Purpose

Sodium Fluoride 0.24% w/w (0.15% w/v Fluoride Ion) Anticavity toothpaste

Helps protect against cavities

Warnings

Keep out of the reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center right away.

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. Children under 6 years of age: use a pea-sized amount and instruct in good brushing and rinsing habits to reduce swallowing. • Supervise children as necessary until capable of using without supervision. • Children under 2 years of age: Consult a dentist or doctor.

Inactive Ingredients: Sorbitol, Hydrated Silica, DI Water, Glycerin, PEG 12, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Disodium Phosphate, Sodium Saccharin, FD&C Blue #1.

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ORALLINE SECURE

sodium fluoride paste, dentifrice

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HUMAN OTC DRUG NDC:55873-001 Product Type Item Code (Source)

Route of Administration

ORAL

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.15 g in 100 g			

Inactive Ingredients	
Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K679 OBS 311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SO DIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 9425516 E2T)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics					
Color		Score			
Shape		Size			
Flavor	MINT (MINT FLAVOR)	Imprint Code			
Contains					

l	Packaging							
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date				
l	1 NDC:55873-001-01	85 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/19 6 6					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part355	0 1/0 1/19 6 6					

ORALLINE

sodium fluoride gel, dentifrice

Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55873-002				
Route of Administration	ORAL						

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	.15 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
SORBITOL (UNII: 506T60A25R)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K679 OBS 311)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: 9425516 E2T)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				

Product Characteristics					
Color		Score			
Shape		Size			
Flavor	MINT (Mint Flavor)	Imprint Code			
Contains					

l	Packaging								
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date					
ı	1 NDC:55873-002-01	85 g in 1 TUBE; Type 0: Not a Combination Product	0 1/0 1/19 6 6						

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part355	0 1/0 1/19 6 6				

Labeler - J.M. Murray Center Inc. (071601108)

Registrant - J.M. Murray Center Inc. (071601108)

Establishment			
Name	Address	ID/FEI	Business Operations
J.M. Murray Center Inc.		071601108	repack(55873-001, 55873-002), relabel(55873-001, 55873-002)

Establishment			
Name	Address	ID/FEI	Business Operations

Dental Technologies, Inc.	148312838	manufacture(55873-001, 55873-002)

Revised: 2/2019 J.M. Murray Center Inc.