

**ORALLINE KIDS- 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 Kids 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

OraLine®  
kids



Berry  
FLAVOR

Fluoride Toothgel  
Net Wt. 4 oz. (113.4g)

For kids of  
ALL ages!

## 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.

**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, Water, Glycerin, PEG 12, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Disodium Phosphate, Sodium Saccharin, Blue 1.

Distributed by J.M. Murray Center, Inc., 823 NYS RT 13, Cortland, NY 13045

Contains no sugar like all ADA-Accepted toothpastes

**Bubble  
Gum  
FLAVOR**

**OraLine®**

**For kids of  
ALL ages!**



**kids**



**Fluoride Toothgel**

**Net Wt. 4 oz.  
(113.4g)**

"The ADA Council on Scientific Affairs' Acceptance of OraLine® Kids Bubble Gum Flavored Fluoride Toothgel 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.

**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, Water, Glycerin, PEG 12, Sodium Lauryl Sulfate, Cellulose Gum, Flavor, Sodium Benzoate, Disodium Phosphate, Sodium Saccharin, Red 40, Red 33.

Distributed by J.M. Murray Center, Inc., 823 NYS RT. 13, Cortland, NY 13045

**Bubble Gum FLAVOR**

Contains no sugar like all ADA-Accepted toothpastes



**OraLinekids**



**Fluoride Toothpaste**

Net Wt. 3 oz. (85g)

The ADA Council on Scientific Affairs' Acceptance of OraLine Kids Bubble Gum Flavored Fluoride 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 Red #40, D&C Red #33.

res

**ORALLINE KIDS**

sodium fluoride gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55873-003
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	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)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)				
<b>Product Characteristics</b>				
Color		Score		
Shape		Size		
Flavor	MINT (MINT FLAVOR)	Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55873-003-01	113.4 g in 1 TUBE; Type 0: Not a Combination Product	01/01/1966	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	01/01/1966		

<b>ORALLINE KIDS</b>			
sodium fluoride gel, dentifrice			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55873-004
Route of Administration	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.15 g in 100 g
<b>Inactive Ingredients</b>			
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)			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			

FD&C RED NO. 40 (UNII: WZB9127XOA)

D&C RED NO. 33 (UNII: 9DBA0SBB0L)

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55873-004-01	113.4 g in 1 TUBE; Type 0: Not a Combination Product	01/01/1966	
2	NDC:55873-004-02	85 g in 1 TUBE; Type 0: Not a Combination Product	01/01/1966	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/01/1966	

**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(55873-003, 55873-004) , relabel(55873-003, 55873-004)

Revised: 2/2019

J.M. Murray Center Inc.