

**ORTHO GUARD- sodium fluoride gel, dentifrice**  
**Massco Dental A Division of Dunagin Pharmaceuticals**

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**ACTIVE INGREDIENT (IN EACH 10 ml)**

SODIUM FLUORIDE 4.4 mg

**Purpose**

Anticavity

**Inactive Ingredients:** Deionized water, monosodium phosphate, phosphoric acid, sodium benzoate, sodium saccharin, artificial coloring, artificial flavoring.

**Use**

Aids in the prevention of dental decay

**Warnings**

- **When using this product,** do not swallow unless to do so by a dentist or physician.
- If more solution is accidentally swallowed than used for rinsing, get medical help or
- contact a Poison Control Center immediately.

**KEEP OUT OF REACH OF CHILDREN**

**DIRECTIONS: Use As Directed**

ADULTS AND CHILDREN 6 YEARS AND OLDER

USE ONCE A DAY AFTER BRUSHING YOUR TEETH WITH TOOTHPASTE. VIGOROUSLY SWISH 10 MILLILITERS (10 ml ON CAP OR 2 TEASPOONS) OF RINSE BETWEEN YOUR TEETH FOR 1 MINUTE THEN SPIT OUT. DO NOT EAT OR DRINK FOR 30 MINUTES AFTER RINSING. INSTRUCT CHILDREN UNDER 12 YEARS OF AGE IN GOOD RINSING HABITS TO AVOID SWALLOWING.

CHILDREN UNDER 6

CONSULT A DENTIST OR PHYSICIAN

**OTHER INFORMATION**

- Store at room temperature.

**QUESTIONS? COMMENTS?**

CALL **1-479-787-5168** M-F 9 am TO 5pm CST


**PACKAGE LABEL**

ORTHO GUARD ANTI-CAVITY FLUORIDE RINSE 0.044% SODIUM FLUORIDE IN AN ACIDULATED PHOSPHATE TOPICAL SOLUTION. MANUFACTURED BY MASSCO DENTAL A DIVISION OF DUNAGIN PHARMACEUTICALS, GRAVETTE AR (479) 787-5168.

NDC 63783-401-16

ANTI-CAVITY FLUORIDE RINSE

**OrthoGuard™**



GRAPE FLAVOR

0.044% Sodium Fluoride  
in an Acidulated Phosphate Topical Solution

Net Wt. 16 fl. oz. (473 mL)

Drug Facts		Directions: Use As Directed	
<b>Active Ingredient</b> (in each 10 mL.)	<b>Purpose</b>	<b>Adults &amp; Children 6 Years and Older</b>	<ul style="list-style-type: none"> <li>Use once a day after brushing your teeth with toothpaste.</li> <li>Vigorously swish 10 milliliters (10 mL on cap or 2 teaspoons) of rinse between your teeth for 1 minute, then spit out.</li> <li>Do not eat or drink for 30 minutes after rinsing.</li> <li>Instruct children under 12 years of age in good rinsing habits to avoid swallowing.</li> </ul>
Sodium Fluoride 4.4 mg	Anticavity		
<b>Inactive Ingredients:</b> Deionized water, monosodium phosphate, phosphoric acid, sodium benzoate, sodium saccharin, artificial coloring, artificial flavoring.		<b>Children Under 6</b>	<ul style="list-style-type: none"> <li>Consult a dentist or physician</li> </ul>
<b>Use</b>			
<ul style="list-style-type: none"> <li>Aids in the prevention of dental decay</li> </ul>		<b>Other Information:</b>	
<b>Warnings</b>		<ul style="list-style-type: none"> <li>Store at room temperature</li> </ul>	
<ul style="list-style-type: none"> <li>When using this product, do not swallow unless told to do so by a dentist or physician.</li> <li>Keep Out Of Reach Of Children. If more solution is accidentally swallowed than used for rinsing, get medical help or contact a Poison Control Center immediately.</li> </ul>			

**Questions? Comments?**  
Call 1-479-787-5168 M-F 9am to 5pm CST

**Manufactured By:**  
**MASSCO DENTAL**  
A Division of Dunagin Pharmaceuticals, Gravette, AR  
(479) 787-5168 • www.masscodental.net

NDC 63783-400-16

ANTI-CAVITY FLUORIDE RINSE

**OrthoGuard™**



ICY COOL MINT FLAVOR

0.044% Sodium Fluoride  
in an Acidulated Phosphate Topical Solution

Net Wt. 16 fl. oz. (473 mL)

Drug Facts		Directions: Use As Directed	
<b>Active Ingredient</b> (in each 10 mL.)	<b>Purpose</b>	<b>Adults &amp; Children 6 Years and Older</b>	<ul style="list-style-type: none"> <li>Use once a day after brushing your teeth with toothpaste.</li> <li>Vigorously swish 10 milliliters (10 mL on cap or 2 teaspoons) of rinse between your teeth for 1 minute, then spit out.</li> <li>Do not eat or drink for 30 minutes after rinsing.</li> <li>Instruct children under 12 years of age in good rinsing habits to avoid swallowing.</li> </ul>
Sodium Fluoride 4.4 mg	Anticavity		
<b>Inactive Ingredients:</b> Deionized water, monosodium phosphate, phosphoric acid, sodium benzoate, sodium saccharin, artificial coloring, artificial flavoring.		<b>Children Under 6</b>	<ul style="list-style-type: none"> <li>Consult a dentist or physician</li> </ul>
<b>Use</b>			
<ul style="list-style-type: none"> <li>Aids in the prevention of dental decay</li> </ul>		<b>Other Information:</b>	
<b>Warnings</b>		<ul style="list-style-type: none"> <li>Store at room temperature</li> </ul>	
<ul style="list-style-type: none"> <li>When using this product, do not swallow unless told to do so by a dentist or physician.</li> <li>Keep Out Of Reach Of Children. If more solution is accidentally swallowed than used for rinsing, get medical help or contact a Poison Control Center immediately.</li> </ul>			

**Questions? Comments?**  
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NDC 63783-403-16

ANTI-CAVITY FLUORIDE RINSE

**OrthoGuard™**



STRAWBERRY FLAVOR

0.044% Sodium Fluoride  
in an Acidulated Phosphate Topical Solution

Net Wt. 16 fl. oz. (473 mL)

Drug Facts		Directions: Use As Directed	
<b>Active Ingredient</b> (in each 10 mL.)	<b>Purpose</b>	<b>Adults &amp; Children 6 Years and Older</b>	<ul style="list-style-type: none"> <li>Use once a day after brushing your teeth with toothpaste.</li> <li>Vigorously swish 10 milliliters (10 mL on cap or 2 teaspoons) of rinse between your teeth for 1 minute, then spit out.</li> <li>Do not eat or drink for 30 minutes after rinsing.</li> <li>Instruct children under 12 years of age in good rinsing habits to avoid swallowing.</li> </ul>
Sodium Fluoride 4.4 mg	Anticavity		
<b>Inactive Ingredients:</b> Deionized water, monosodium phosphate, phosphoric acid, sodium benzoate, sodium saccharin, artificial coloring, artificial flavoring.		<b>Children Under 6</b>	<ul style="list-style-type: none"> <li>Consult a dentist or physician</li> </ul>
<b>Use</b>			
<ul style="list-style-type: none"> <li>Aids in the prevention of dental decay</li> </ul>		<b>Other Information:</b>	
<b>Warnings</b>		<ul style="list-style-type: none"> <li>Store at room temperature</li> </ul>	
<ul style="list-style-type: none"> <li>When using this product, do not swallow unless told to do so by a dentist or physician.</li> <li>Keep Out Of Reach Of Children. If more solution is accidentally swallowed than used for rinsing, get medical help or contact a Poison Control Center immediately.</li> </ul>			

**Questions? Comments?**  
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**ORTHO GUARD**

sodium fluoride gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63783-400
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	4.4 mg in 10 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE</b> (UNII: 593YOG76RN)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

**Product Characteristics**

Color	Score
Shape	Size
Flavor	Imprint Code
MINT (ICY COOL MINT)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-400-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1989	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/01/1989	

**ORTHO GUARD**

sodium fluoride gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63783-401
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	4.4 mg in 10 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE</b> (UNII: 593YOG76RN)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE (GRAPE)	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63783-401-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1989	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M021	01/01/1989	

**ORTHO GUARD**

sodium fluoride gel, dentifrice

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63783-403
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	4.4 mg in 10 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-403-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1989	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	01/01/1989	

**Labeler** - Massco Dental A Division of Dunagin Pharmaceuticals (008081858)

**Registrant** - Massco Dental A Division of Dunagin Pharmaceuticals (008081858)

Establishment			
Name	Address	ID/FEI	Business Operations
Massco Dental A Division of Dunagin Pharmaceuticals		008081858	manufacture(63783-400, 63783-401, 63783-403)