

## **MEDACTIVE PATIENT FRIENDLY STANNOUS FLUORIDE RINSE- stannous fluoride**

**Integrate Oral Care, LLC.**

*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.*

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### **Active Ingredient**

Stannous Fluoride 0.1%

### **Uses**

Aids in the prevention of dental decay.

### **Warnings**

- When using this product, do not use longer than four weeks unless recommended by a medical doctor and/or dental professional.
- If more than used for rinsing is swallowed, seek medical attention or contact a Poison Control Center immediately.

### **Directions**

**Use immediately after preparing the rinse as follows:**

#### **Adults and children 6 years or age and older:**

- Place both thumbs on **Blue Chamber No. 1** and Press down firmly to squeeze fluoride into **Chamber No. 2**.
- Gently Shake.
- Snap Tab to Open by bending at line on the cap. Dispense half of mixture into the mouth and Rinse for 30 seconds. Spit.
- Gargle with remainder of mixture for 30 seconds. Spit.
- Avoid any food or drinks for at least 15 minutes after use.

#### **Children under 6 years of age:**

- Consult your medical doctor and/or dental professional.

### **Other Information**

- This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dental professional.
- Do not refrigerate. Store at room temperature.
- See Rinse or box for expiration date.

### **Inactive Ingredients**

dimethocone, EDTA, FD&C Green No. 3, flavor, glycerin, poloxamer 407, potassium sorbate, sodium saccharin, sorbital, sucralose, water

### **Questions or comments?**

**1-866-887-4867** M-F 9 am - 5 pm EST or **[www.integrateoralcare.com](http://www.integrateoralcare.com)**

Keep out of reach of children.

## Purpose

Cavity Protection

## Principal Display Panel - 30 Dose Packs



MedActive

Oral Care Redefined

Patient-Friendly

Orange Crème

Stannous Fluoride **Rinse** with ULTRAMULSION

Mild Formula

**30 Dose Packs**

NET CONTENTS: 30 DOSE PACKS 31.2 FL OZ (923 mL)

**IMPORTANT:** Read directions for proper use.

NDC 49741-1005-3

## Principal Display Panel - 10 Dose Packs



MedActive

Oral Care Redefined

Patient-Friendly

Orange Crème

Stannous Fluoride **Rinse** with ULTRAMULSION

Mild Formula

**10 Dose Packs**

NET CONTENTS: 10 DOSE PACKS 10.4 FL OZ (307 mL)

**IMPORTANT:** Read directions for proper use.

NDC 49741-1006-2

## MEDACTIVE PATIENT FRIENDLY STANNOUS FLUORIDE RINSE

stannous fluoride kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49741-1006
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49741-1006-2	10 in 1 BOX	07/31/2014	
1		1 in 1 CARTON; Type 0: Not a Combination Product		
2	NDC:49741-1006-3	30 in 1 BOX	07/31/2014	
2		1 in 1 CARTON; Type 0: Not a Combination Product		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 KIT	3.7 mL
Part 2	1 KIT	27 mL

### Part 1 of 2

#### CHAMBER NO. 1

stannous fluoride concentrate

### Product Information

**Route of Administration** ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	6.3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 1 mL
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	1 mL in 1 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3.7 mL in 1 KIT; Type 0: Not a Combination		

Product
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/31/2014	

## Part 2 of 2

### CHAMBER NO. 2

stannous fluoride diluent emulsion

## Product Information

Route of Administration	ORAL
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## Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	ORANGE (Orange Crème with ULTRAMULSION®)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		27 mL in 1 KIT; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part355	07/31/2014	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/31/2014	

**Labeler** - Integrate Oral Care, LLC. (063540457)

Revised: 12/2021

Integrate Oral Care, LLC.